HIT Policy Committee Workgroup
Final Transcript
November 19, 2010

Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director
Good afternoon, everybody, and welcome to the 18th meeting of the HIT Policy Committee. This is a Federal Advisory Committee, which means there will be opportunity at the end of the meeting for the public to make comment, and the transcript of the meeting will also be posted on the ONC Web site. A reminder to committee members to please identify yourselves when speaking. Let's go around the table with introductions beginning on my right.

Jodi Daniel – ONC – Director Office of Policy & Research
Jodi Daniel, ONC.

Adam Clark – FasterCures – Director, Scientific & Federal Affairs
Adam Clark, FasterCures.

Neil Calman - Institute for Family Health - President & Cofounder
Neil Calman, Institute for Family Health.

Judy Faulkner – Epic Systems – Founder
Judy Faulkner, Epic.

David Lansky – Pacific Business Group on Health – President & CEO
David Lansky, Pacific Business Group on Health.

Paul Egerman – Software Entrepreneur
Paul Egerman, software entrepreneur.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Paul Tang, Palo Alto Medical Foundation.

David Bates - Brigham and Women's Hospital - Chief, Div. Internal Medicine
David Bates, Brigham & Women's and Partners.

Christine Bechtel - National Partnership for Women & Families – VP
Christine Bechtel, National Partnership for Women & Families.

Marc Probst – Intermountain Healthcare – CIO
Marc Probst with Intermountain Healthcare.

Deven McGraw - Center for Democracy & Technology – Director
Deven McGraw, the Center for Democracy and Technology.

Art Davidson - Public Health Informatics at Denver Public Health – Director
Art Davidson, Denver Public Health, Denver Health.

Madhulika Agarwal – VA – Chief Patient Care Services Officer, Office of Patient Care
Madhulika Agarwal, Department of Veterans Affairs.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

Larry Wolf, Kindred Healthcare.

Scott White – 1199 SEIU – Assistant Director & Technology Project Director
Scott White, 1199 SEIU.

Jim Borland – SSA – Special Advisor for Health IT, Office of the Commissioner
Jim Borland, Social Security Administration.

Judy Sparrow – Office of the National Coordinator – Executive Director
And on the phone, I believe we have Connie Delaney.

Connie Delaney – University of Minnesota School of Nursing – Dean
Connie Delaney, Minnesota.

Judy Sparrow – Office of the National Coordinator – Executive Director
Gayle Harrell?

Gayle Harrell – Florida – State Representative
Gayle Harrell, newly elected representative from the state of Florida.

Judy Sparrow – Office of the National Coordinator – Executive Director
Congratulations, Gayle. Any other members on the line? Okay. With that, I'll turn it over to Dr. Tang.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Good morning. I think what we'll do is we'll rearrange the agenda a little bit before Dr. Blumenthal arrives. The first order of agenda is to not only congratulate Gayle, but also to welcome Dr. Agarwal, who is the new representative from the VA services. She is the chief of patient care services, and that's a lot of lives and, I mean, budgets that start with the billions. But in any rate, so she's been an advocate of EHR for a decade or more. We're just delighted to have her join the group, so thank you very much.

With that, the next bit of agenda is to entertain a motion to approve the minutes.

M
So moved.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Second?

M
Second.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
All in favor?

M
Aye.

M
Aye.

W
Aye.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Any opposed? Any abstention? Good. So the agenda is, we're going to do three major things. One, we'll have a brief update from the quality measures workgroup. David Lansky will inform us on that

activity, and that's got a lot of subgroups in it and driving towards getting some new kinds of quality measures that are going to help us charge forward in the new era. John Lumpkin will update us on the NHIN governance workgroup recommendations, and that's a for action piece. Then after lunch, Micky and David will talk to us about the information exchange workgroup recommendations on provider directories. Finally, Deven and Paul Egerman are going to talk to us about the privacy and security tiger team recommendations. We'll conclude with public comments.

I think we will go ahead and proceed, and just we'll stop a moment when Dr. Blumenthal arrives to make his remarks, so do you want to proceed with David Lansky and the update on the quality measures workgroup, please?

David Lansky – Pacific Business Group on Health – President & CEO
We're doing a very short update today, not because there hasn't been a lot of work done, but because our agenda is so full, and I think we're at a weigh station in our work, in the quality measures workgroup. You have in your packet today the slides, as well as a two-slide handout that updates a couple of elements on two of the workgroups or tiger teams rather. So let me just give you a quick update.

You're recall that this group has been meeting for three months or so and, about midstream, we convened six tiger teams, small taskforces, which included both workgroup members and non-workgroup members, subject matter experts who could help us think through the opportunity to use quality measures for meaningful use that would go beyond the initial battery that we used for stage one. In broad strokes, we were trying to go beyond the process measures that had been most easily available for the state one work and see whether we could drive toward more measurement of patient outcomes and clinical outcomes as part of our strategy to achieve all the goals of the HITECH law and of our broader charge. So we have this wonderful group of people from a wide spectrum of stakeholder areas. They broke up into the six tiger teams.

The tiger teams then produced measure concepts, areas where they thought there were currently gaps in our ability to produce measures that were demonstrating meaningful use of health IT. As you recall from the last time we presented, there was a set of criteria that particularly focused on things like HIT sensitive measures and, as well, HIT enabled measures. But we're really focused on sensitive measures, that is, those that would be reflective of improvements in care that might have been assisted by the successful use of health IT.

So we broke up into the six tiger teams, and here in kind of a brief recap is where we've come out. Here is the summary of the outcomes from the patient and family engagement tiger team. You see, they produced within that domain, a set of sub-domains on the right side of the slide. Within those sub-domains, measure concepts, which they believe are amenable to measurement for meaningful use. What we're doing after I'll quickly recap these, after we identify these areas of measurement work, we're going out to the measurement community and saying, have you got measures that are well developed and could easily be adapted for the purposes of meaningful use? If so, please give us documentation and information that would enable ONC and CMS to consider whether they would make sense for meaningful use.

We will be doing a request for comment in response to what you're seeing now on the slide and the other tiger team reports. The request for comment will go out November 29th is our target, so really just a week or two, and then we'll give people most of December. We don't have a final date to respond to that request for comment. We'll digest that input and then potentially ONC will go out for additional solicitation to get more specific development work on these measures. So for today, I just wanted you to understand where we are in the process and have a chance to become familiar with these concepts that emerge from the tiger team work.

In the area of patient and family engagement, you'll see a great focus on patient's ability to self manage, their ability to understand and act on their own behalf, knowledge of self-efficacy, self-management, to be fully engaged as partners in decision-making and, of course, the IT platform is a key support to that process. Measures of whether patient preferences have been taken into account and whether patients

are reporting positive experiences of care, directly asking patients about their health outcomes, as well as progress against risk status and functional improvements, and a broader measure that we're interested in of whether the care system is helping patients connect to the larger community to manage and improve their health.

The notes in italics here on this slide are just to highlight that we know that there are other federal programs that are very busy developing measures for areas of relevance to themselves, and so we are coordinating ONC staff, as directly coordinating with other federal measurement efforts, to make sure that we don't go off on a branch to try to develop in this example, measures of patient experience when we know there are other teams in the federal program doing the same work. So there'll be a good attempt to coordinate the measurement identification or development work in these areas that are italicized. That's the patient and family engagement tab.

Here on clinical appropriateness, and again, you have the revised handout in your packet, you'll see emphasis on readmissions on length of stay, ambulatory care, sensitive, preventable hospitalizations, appropriate use of some procedures such as diagnostic imaging, some chronic care management coordination tools looking at appropriate medication use and adherence efforts, some focus on generic versus brand name utilization, and then you see a battery of cardiovascular, preventative interventions down at the bottom there. Under care coordination, an array of measures, the first one on having a comprehensive care plan in the EHR and whether or not the care team is successful at helping people attend to the elements of that plan, addressing an advanced care plan as part of shared decision making, looking at the success of self care management plans for patients where that could be an efficacious tool, medication reconciliation, again looking at patient reports of their experience of care coordination, as well as individual care settings. Looking at overall receipt of coordinated care by the team and the receipt of clinical summaries by the patient, and then timeliness of response to clinical information.

Under patient safety, looking at adverse drug events and coordinating with the FDA program. Looking at specific patient safety for specific therapies like Warfarin for chronic medication therapy, patient reported adverse events, and looking at the methodologies for that, hospital associated infections, ETE prophylaxis, and falls. Finally, population and public health, use of availability of services to promote healthy lifestyles and with these three target areas. Alcohol screening, mental health screening, specific focus on blood pressure, including the emphasis to develop measures that look at longitudinal change and longitudinal management of both blood pressure and blood glucose, and then in an attempt to look at the methodologies for health equity and disparities. It's a very interesting, frankly, methodology work on how we could think about and institutionalize measures of disparities that that team has discussed.

Then there's a battery of sort of parking lot issues that we want to look at and solicit public comment on, preventable emergency use, adherence to practice standards in a couple of target areas in cardiac and cancer. Looking at combining quality and cost measures at different levels and sites of care. Looking at near misses in medication management. Looking at near misses in patient identification. This is an artifact of health IT utilization. Again, on health IT, safety measure at the bottom, looking at the potential way of measuring common IT induced errors, if you like.

As you can see, that's a lot. We're, at this point, not by any means intending that meaningful use in stages two or three would capture everything we've just listed. We're actually hoping that the measurement world will come back to us with some elegant, crosscutting techniques for measuring multiple of these concepts with single measures or small batteries of measures. Today, we certainly didn't hope to have the committee try to look through the details of this, but just give you a chance to understand the scope of what we're about and the process we're engaged in. I imagine we'll be back here in maybe January or February with some results from the public comment process. We particularly thank the ONC staff for really doing phenomenal work trying to lead all of us through this process in just a couple months and come up with this relatively compact set of measurement domains.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Are there any comments or questions before we turn it back over to Dr. Blumenthal? I have a question on, so when you are going after a request for public comment, is it on the concepts, or you're expecting also people to propose specific measures or perhaps both?

David Lansky – Pacific Business Group on Health – President & CEO
We'll be providing them with a grid effectively as a response tool. The grid actually asks them if they are able to, to identify specific measures in use, which would address these concepts, or measures that are close to being implementable and how we would then go to work with the developers or owners of those measures to further explore their usability and then any literature citations and so on that might be relevant to that proposal. Where there isn't a measure well developed, we're certainly interested in them telling us what they think would be the approach to address that. Given the relatively short timeline we're all working on, we're not looking for blue sky development opportunities here. I think we're looking for well developed concepts and measures.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Will the final output of your group be at the concept level or measures of wherever you can get or as far as you can get in each area?

David Lansky – Pacific Business Group on Health – President & CEO
Well, I think I would still ask Dr. Blumenthal. I think our responsibility is to recommend back to this group whatever measures we think are viable for stages two and three that are realistic or whatever steps might be needed to get them from here to there.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Any other comments, questions? Okay. Let's go back to, I forgot one logistic reminder. The next meeting is December 13th. It originally was scheduled for a conference call, but we had changed it to face-to-face because there are a number of important recommendations that we wanted to have feedback, and face-to-face is much better to get that kind of feedback from the group, so just a reminder. Let me turn it back to Dr. Blumenthal for his opening comments then.

David Blumenthal – Department of HHS – National Coordinator for Health IT
I apologize for being late. I don't want to interrupt the flow here. I just want to add my welcome to everyone. The note that we are well into the continuing discussion about a whole series of very important problems that need to be resolved while we are implementing stage one of meaningful use and, as part of the process of moving to stage two, so I think the most important thing at this point is that we leave time for the presenters, so I'm going to pass the microphone back to Paul, who is more in the flow of the meeting.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Next up is Dr. John Lumpkin, who is chair of the governance workgroup.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Good morning. I have to admit that I started out my career in medicine as an anesthesia intern, and when I took on this job, I thought that here was an opportunity to put more people to sleep than I did during my internship. But contrary to that notion, this has proven to be quite a very interesting process with, as you know, a very short term, intensive process. We think that we've come to a good place. We've had a number of meetings, and I would like to thank the members of the workgroup for their efforts. We've actually probably had about four meetings within the last week just to try to hone all of these recommendations down.

What I'm going to do today is talk about our recommendations and then list a couple of issues that we have not been able to resolve as part of the recommendation, and then allow you to take your action and move forward. I would like to point out on our committee that we did have a broad group of committees. Two of the members, Laura Adams and John Glaser, are members of NHIC. Two members, Michael Matthews and John Mattison, are on the coordinating committee that is managing exchange through the DURSA. I also wanted just to thank Mary Jo and Mariann Yeager for their stellar work. It seems like

every time we'd have a meeting, the next day we would have a revised set of slides. We could not have gone through this process without their stellar effort.

Let me remind you about how we went through this process. Basically we stood up the committee in late August. We had our first hearing in September on September 28th. We presented to you on October 20th our first phase set of recommendations, which were based upon the environmental scan in the hearing that we conducted. The focus of that recommendation was what should be part of this governance mechanism. We are now coming back to you with the who and how that governance mechanism should be established, so let me put this into context.

The definition of the National Health Information Network, which is the Office of the National Coordinator Network, and once again I'm reminded that as I'm using the term, Nationwide Health Information Network, this is not a term that ONC has coined for further use, but is a placeholder term that are using as part of our recommendations, which is a set of policies, standards, and services that enable the Internet to be used for secure and meaningful exchange of health information to improve health and healthcare.

The first question we said, well, okay, that's a good definition. Let's play with that a little bit, so we can answer the question, what is this Nationwide Health Information Network? We described it in our thinking as an environment of trust and interoperability that's created by the standards, services, and policies of the Nationwide Health Information Network, and it is a preferred approach for exchange of health information nationwide, supported by the federal government with strong incentives to vigorously promote adoption. We recognize that participation in the Nationwide Health Information Network is and cannot be mandatory under current law, even though we do believe strongly that it is the preferred mechanism for exchange to occur.

The second question is when is exchange considered within the Nationwide Health Information Network and subject to governance? We felt that there were two instances. When that exchange complies with applicable standards, services, and policies, such as what a term that we are going to be using fairly frequently, what we call the conditions of trust and interoperability, and when those exchanging health information assert that they're doing so under the auspices of the Nationwide Health Information Network.

When is exchange not considered to be part of the Nationwide Health Information Network and, therefore, not subject to governance? When it's not asserted to be compliant, and if there is compliance of only a portion of the applicable requirements. In other words, it complies with the technical requirements, but not with the policy.

Who should be part of this governance process? Any entity, large or small, or aggregation of entities large or small that engages in exchange of health information and asserts itself as being part of the Nationwide Health Information Network as being compliant, and is recognized to have met the conditions of trust and interoperability. Why would entities want to be part of the health information network? We think that there are a number of reasons why. The example that comes to my mind is the person who lives or is practicing in Paducah, Kentucky, and wants to exchange information with somebody in Poughkeepsie, New York. The likelihood that they know anybody in Poughkeepsie is fairly slim, but the fact that they can identify that they're complying with the same conditions of trust and interoperability enables them to feel some comfort and trust in exchanging health information.

The second is it provides a benchmark for entities that wish to qualify for federal contracts in exchange, much as what we now see with exchange in the current iteration, and entities that they believe that they would be either competitively advantaged in the marketplace or they would meet widely recognized conditions of trust and interoperability. Then the last one is because we are expecting and hoping that the federal government will provide all sorts of incentives, both to encourage the broadest set of entities to participate.

What do we find in our adhering related to this that there was clear direction towards leverage and coordination across existing federal authorities. That there was a need for strong federal leadership and engagement and participation, and that the federal role was needed to set national level policy to oversee

and coordinate across a set of governance processes that comprise of governance and assure that Nationwide Health Information Network governance includes the ability to evaluate, learn, and adapt on an ongoing basis. We thought that was critical because essentially we're putting tires on a moving vehicle, and unless we understand that and put that into the governance process in the beginning, we won't create the kind of governance that will morph over time, as in fact we see that exchange begins to morph.

In addition, we recognize there'll likely be a variety of approaches in multiple levels of coordination and validation and enforcement, and that government mechanism should reflect that. There were some differing views regarding the need for nation level validation mechanisms such as certification and accreditation, and some in our public hearing recommended that others caution that it might be premature to do so. Also, the need for nationwide level coordination across a wide range of stakeholders to build consensus and form development of the requirements, and the recognition that enforcement occurs at various levels and with other federal authorities, and that we wanted to minimize the burden on those who wanted to engage in exchange, and so coordination amongst the federal levels and other levels are going to be critical to be able to do that.

As I wanted to remind you about our level one recommendations, the level one recommendations, the first where we developed a set of nine principles for the Nationwide Health Information Network. I just want to highlight a couple of those because I did present them the last time I was here. We particularly wanted to raise the issue of transparency and openness, inclusive participation and adequate representation, and we continuously emphasized including consumers. We felt that consumers had the ability and should be engaged in a meaningful way in this governance process.

The concept of federated governance and devolution that decisions should be at the point where the individuals or the entities involved have the largest amount of knowledge within the construct of a federal direction. Number eight, to promote and support innovation, we thought was a critical component because, again, this is a process that is an evolution. Finally, in order to do that, it should be a learning and continuous improvement process. The other recommendations for phase one, and I'm just going to point one of these out, not to go over the whole slide because you can read that, but the governance of the Nationwide Health Information Network should include opportunities for broad stakeholder input, including consumers on strategic directions. That was an issue that we came back to again and again.

So the objectives, we felt that the objectives of governance were to improve health while establishing trust to assure interoperability while protecting innovation, and that we believe that there are certain functions to establish policies for privacy, security, interoperability, and to promote adoption of the Nationwide Health Information Network. That is not to identify, for instance, with the specific technical requirements of interoperability. We're not proposing that we're going to recommend this particular code set or this particular transaction standard, but the mechanism for the approval of those, the policies for those.

To establish the technical requirements that assure policy and technical interoperability, establish appropriate mechanisms to assure compliance, accountability, and enforcement, and to provide oversight of the mechanisms so that we can assure that they are flexible enough to recognize that we're dealing with the changing environment. That's where we were when we reported to you just a month ago. Let me tell you where we've gone since then in our second phase.

The first thing that we did in the second phase is that we asked the questions on their slide. We wanted to know what was out there and to identify the gaps. What are the existing entities, perform this function, and if so, what are they doing? Can they scale up? What are the essential functions? Should the federal government perform that directly or delegate, and delegate it to whom? If there's a new entity, what kind of entity should that be?

We had 234 commenters: 33 responded to a blog, 201 by e-mail. We did get out some awareness of the fact that we were seeking input through the standard federal ways, as well as some of the media that is specifically focused on health information technology. What we found were comments and a need for public education and use of plain language. It's fairly clear that I kind of thought that when I talked to this

with my wife or some of my colleagues at work, and they say, I think the response I got back was boy this stuff is really dense. And these were the folks who were interested in HIT where I work. That sort of echoed with the public, and I think we're going to, at some point, need to have some clear way of communicating what we're actually talking about.

That more emphasis needed to be placed on patient safety, that the greatest concern, and this wasn't a surprise because we've seen this from back in the days when I was at NCVHS that privacy and security was a very strong concern, and we had a number of comments on that. Many thought to leverage the existing mechanisms where appropriate, and we felt that that was part of our recommendations. Some of the key findings related from the public comment, highlighted again the state and federal partnership, the importance of recognizing that some states like Minnesota and New York and others are already beginning to move forward on the governance front, and we needed to have the flexibility to make this an integrated whole rather than just having parts that are not working together.

That the public/private collaborative structure to act as a convener and support adoption of the Nationwide Health Information Network, and the need for national level policies and standards with input from some committee called the HIT PC, and then the national accreditation program for qualified entities. There were also suggestions made for leveraging existing governance structure, including interoperability with the SDOs, the validation with CCHIT and others, and recognizing at the federal level that there are other policies and practices that are governed by other federal agencies, as well as the Data Use and Reciprocal Support Agreement, the DURSA.

What does the ecosystem look like? We identified that again the objectives are to engender trust, to encourage interoperability, and to foster innovation. That would enable us to yield the results that we believe are important from the Nationwide Health Information Network, which is to have the right information available at the right time so that healthcare providers and caregivers and their patients can make the decision that's in the best interest of their patient and do that in a collaborative way.

There were four domains, large domains, which we though impinged upon the fifth one. The policies and eligibility criteria, establish technical requirements to oversee governance, and insure compliance, accountability, and enforceability. The first area was to provide support for implementation, which is a little bit more granular level of governance, but recognizing that there needs to be a give and take, as we're doing this implementation, to understand what's going on with implementation and to provide some assistance and coordination, and so that led us to identify some of the gaps within that context.

As you can see on this slide, for those of you who have it in color, the gaps are listed in red. The first area was the policies and eligibility criteria. We felt that there are existing federal authorities that govern the exchange of certain types of information, that they include a number of agencies, which requires some coordination, and the Office of the National Coordinator, along with advice from the FACAs. That's what we had. The gaps were the mechanisms with clear authority to identify, prioritize, and recognize non-technical HIN conditions of trust and interoperability, and additional coordination among the federal agencies was needed.

The second area was establish technical requirements for the HIN. We felt that there were some existing structures with the Office of the National Coordinator with input from the evolving standards and interoperability framework and advice from the FACAs. The gap was there is a mechanism with clear authority to identify, prioritize, and recognize the HIN technical conditions of interoperability and trust, and trust and interoperability, while allowing innovation.

The fifth area was providing support for implementation of the conditions of trust and interoperability, and we felt that there was a gap there. There was a mechanism to provide consistency in application while allowing innovation. A need to have representative input for broad community of stakeholders, again including consumers was a particular focus. The fifth area was the validation of compliance with the conditions of trust and interoperability, and we felt that there was some currently existing work there with the Office of the National Coordinator, leveraging the meaningful use criteria and program, but the gaps were a mechanism to verify compliance and to recognize entities to determine eligibility and verify

compliance. And the last area was oversight. We felt that ONC is playing a role, but there's a gap in formally establishing oversight processes for the health information network.

Moving forward, what were our recommendations? I'm going to talk about a couple of general ones and then get into some specifics. The first is that in order for the HIN to be successful, there must be strong federal leadership, support, and engagement in the health information network. Second is that requirements for trust and interoperability are essential to the success of the HIN, while the federal government should establish the fundamental conditions to insure the public good. Other governance entities should have specific appropriate roles in providing input to the development and validating the entities that have met them in supporting their consistent implementation.

Certain aspects of governance such as accountability, dispute resolution, enforcement and oversight should apply across the recommended governance roles in a manner appropriate to that role. As you will see on the next slide, we're going to talk about three major roles that we're going to have recommendations on, and we felt that the issues of dispute resolution and enforcement as oversight should apply across to all three roles. Those three roles are the federal role, a nongovernmental role, and a validation role. I will talk in some detail about the federal role, but it's to establish the HIN conditions of trust and interoperability, to identify, prioritize, and recognize HIN policies for trust and interoperability, and establish technical requirements, to identify applicable conditions of trust and interoperability, to establish, where appropriate, other criteria or eligibility that need to be developed, and coordinate across federal agencies and oversee the governance process.

We're recommending a nongovernmental role for your approval to provide support for implementations of the conditions of trust and interoperability, to identify the issues of implementation and make recommendations to appropriate federal authority, and to obtain input from a broad range of stakeholders, including consumers, regarding the conditions of trust and interoperability and the validation process. The third role was verifying whether the conditions of trust and interoperability are met, the validation role, to verify compliance, and to address issues with noncompliance.

The attributes at the federal level, they're all on this slide, but I'm just going to highlight a few. We feel that the federal level needs to be accountable for assuring public trust, the ability to coordinate across the federal government as a recurring theme, and that coordination across the various governance roles is a very significant role that we are recommending should be at the federal level. The attributes of a nongovernmental organization role, that it should have sufficient authority for delegated responsibilities. It should be open and transparent. There should be broad stakeholder community representation, including consumers. There should be a balance of interests. There should not be overweight towards one particular set of interests, providers, vendors, others, or exchanges, that it should be balanced.

Key attributes for the validation role, that it has sufficient authority for results to be binding, to authorize, deny, and revoke, that leverage where appropriate existing mechanisms, allow for differing routes to validation based upon appropriate considerations, types of conditions of trust and interoperability, of the nature of the exchange, or the entity that's doing the exchange. We believe that one of the key attributes is that it should be objective. It should be repeatable, better efficient, effective, and able to scale at the national level.

Let's talk a little bit about our recommendations on the conditions of trust and interoperability. That the ONC, with advice from the FACAs and input from the designated, non-government entities should identify, prioritize, and establish a set of policies and eligibility criteria and technical requirements for the HIN. These are the conditions of trust and interoperability. That there should be a set of universally required conditions of trust and interoperability that apply across all the scenarios with a focus on those elements critical to engender trust, promote interoperability, and address barriers to nationwide exchange while remaining technically agnostic. That there may be conditions of trust and interoperability that apply in particular circumstances based upon particular functions, and there should be a mechanism to wave certain required conditions of trust and interoperability if necessary to facilitate experimentation and innovation. I wanted to highlight that particular point that the discussion about earlier one of our principles

about innovation really mandates that there's some mechanism to allow experimentation to occur, and learn the lessons from those, and that can be done through a waiver process.

That the governance should recognize that additional requirements may be specified for particular entities or groups that may or may not be part of the conditions of trust and interoperability. That may be a community of exchange or a group of entities that are exchanging with some common background or format or approach to exchange. So the potential areas and some of the example topics, I won't go into these, but as you can see, they fall within privacy, security, eligibility, interoperability, policies and technical requirements.

Further on this federal role, that the Office of the National Coordinator should insure coordination across federal activities and authorities and identify needs to strengthen them for effective governance. Coordinate to establish incentives to vigorously promote the use of the HIN. This was an issue that we, again, hit on a number of times. If they're, again, recognizing that this is not an environment where participation in the HIN can be mandated, but we did feel that this was a preferred use, and the way to do that was that there would be vigorous activities at the federal level to encourage and promote the use.

That the federal role would include the establishment of conditions of trust and interoperability, develop the validation criteria to reflect the conditions of trust and interoperability. Those are the criteria that would be used by the validation entity. Promote sufficient authority; provide sufficient authority to the coordination, the NGO entity to insure effective actions and oversight, and so delegation of authority and oversight. Recognize overarching validation entity and oversee that, so again, recognizing validation process and oversight. Monitor and highlight innovation, and address governance barriers too. It's a look at where innovation is going, to highlight that, and to identify where there may need to be governance changes if they're creating barriers, and oversee the governance ecosystem.

Federal entities should be expected to meet the conditions of trust and interoperability, as any other entity exchanging through the health information network. Enforcement mechanisms under available law and federal authorities should be leveraged as applicable to assure compliance with the conditions of trust and interoperability for those who have chosen to exchange in that environment. That state authorities across all relevant domains need to be recognized and coordinated and harmonized.

The role for the nongovernmental organization should be established, and we put in parentheses entities because that's one of the open questions that I will list at the end, which I'm hoping to get to soon. Sorry. It should be established and recognized as existing and provided, so non-government entity or entities should be established or recognized if it's existing. So we are not saying that we have identified a specific entity. It may be a new entity. It may be an existing entity. That they be given the authority necessary to support the implementation of the conditions of trust and interoperability.

Their role would be to identify implementation issues and make recommendations to the appropriate federal body. Is implementation consistent with the goals and governance principle and objectives? Is it appropriately being devolved? Does implementation negatively impact certain entities, impede competition or create barriers through exchange? These would be within the scope. To create broad stakeholder community engagement, to carry some weight, and we believe that this should carry some weight with the Office of the National Coordinator and those stakeholders, again, with the focus on assuring meaningful community, consumer engagement, and to provide input to the Office of the National Coordinator and validation entity or entities on performance criteria.

The recommendation on the validation role, that there should be a recognized national validation entity or entities to verify that applicable conditions are established by the Office of the National Coordinator are met. An important component of this is that we wanted to emphasize that it's important to minimize the burden on those who are being validated. So where there's a choice to do a little or a lot, we would prefer a little, minimization. The responsibilities are to apply established and applicable eligibility criteria to determine eligibility, and there's eligibility criteria established at the federal level. To verify the systems used to exchange through the HIN meet the conditions of trust and interoperability. To allow other equivalent certification and validation processes to satisfy HIN validation, including validation by a group,

a certification of electronic health records, state HIE certification, accreditation programs, other things. We want to recognize what's currently there. We don't want to create a nested system where you get validated by your HIE, and then you have to get validated by the validation entity.

To verify that practices are consistent with applicable policies, to issue validation and decision to approve, deny, revoke, as authorized, and to investigate possible noncompliance and take appropriate, remedial action. There should be an overarching validation authority established or, if existing, granted the authority to facilitate the HIN validation. This means overseeing the validation process, determining whether there should be one or multiple validation bodies based upon identified needs, capacity, and capability. Accredit HIN validation bodies like the approach that's used for meaningful use EHR certification and oversee their activities. Establish equivalency criteria to recognize multiple pathways through validation that I talked about through participation in a body that is itself validated. Establish or recognize other non-accreditation approaches and monitor them to assure coordination and consistency with the conditions of trust and interoperability.

We see an interplay between the three roles that we're talking about, between the federal role, the nongovernmental role, and the validation role, and that interplay would be uniform throughout them. A short summary slide of what those roles are, which is for those who like pictures, I won't go into the details of that. It summarizes what we've talked about.

Let me suggest that there are a couple of open questions and then end. The first question is that given that the ONC should determine applicability, universal conditions of trust and interoperability, to what extent should entities and groups be able to further specify conditions of trust and interoperability? If they do, should they be added as conditions, be adopted by the HIN if a subgroup wants to use those? Then, finally, regardless of whether they're considered inside or outside, should these added conditions be subject to review or monitoring for potential impact to competition, impediments to exchange? Again, we did not have an opinion one way or the other due to the timeframe in which we were bringing these forward. It might have taken another couple of months to come to that resolution.

Should there be one or more nongovernmental entities? As you saw throughout the report, I noted at points that we talked about entity or entities, and we could not resolve whether that should be one or multiple. Then, finally, who should be validated? There are some open questions related to what are the size of the entities, how to implement while avoiding burdens that might discourage some entities or prove too costly in resource in a constrained environment. Then who should pay for the cost of developing and maintaining the validation mechanisms is also something that we didn't recommend.

It's a lot of stuff. We did a lot of work. I would like to point out that, again, this was a team effort. We had a lot of discussion. We are making our recommendation to you with the understanding that we did have a diverse group of committee members.

David Blumenthal – Department of HHS – National Coordinator for Health IT
John, thank you very much for that presentation and for your leadership of this group, and I'm pleased that at least it didn't put you to sleep, even if that thought might have occurred to you at times during this activity.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I might have wished that somebody had put me to sleep.

David Blumenthal – Department of HHS – National Coordinator for Health IT
This is actually, of course, extremely important work. Your report has teed up a lot of very major conceptual issues that are fundamental to the enterprise that we're all about. Even though they have titles and terms of reference that are not exciting, they are really fundamental, foundational to what we need to accomplish. They have to do with assuring that the public trusts what's the exchange of health information and that all the fabric that goes on to making that trust possible, and then also assuring that the many organizations likely to be engaged in exchange in the United States can work together, can exchange among themselves, can do so in a predictable way and a sustainable way, and all those things.

I had many questions, but the one I'd like to lay out to start with has to do with the sequence of roles that you've outlined: the federal role, the implementation role, and the validation role. It's particularly the validation role is pretty straightforward. If the federal government is going to recognize in some way exchange entities and in the nature of consumer protection, public assurance, assurance of functioning, recognize those and say, yes, these are doing it. They're okay. They fall within the NHIN. We need to figure out if that's true or not, and we need to have a way of correcting deficiencies or, in the extreme, be validating a group that's really not living up to its requirements. The federal role is, I think, I understand that. It's the middle role, the implementation role that I could use some clarification about.

The way it was described, it sounded a lot like a place where discussions could take place and lessons could be learned outside government. But it didn't seem to have any particular enforcement authority. It seemed an advisory group to ONC, maybe an advisory group to the validation role. Can you elaborate a little bit on what the core critical functions are in the scheme for the implementation group?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Thank you for that question. This is probably the one area that led to the largest amount of debate and discussion within the workgroup. We, I think, in a number of iterations, for those who may have been following this through the open meetings, we initially called this a coordination role. There was a fair bit of concern that giving that much authority to an entity that was nongovernmental to be able to resolve disputes might be inhibitory at this particular point in the process. But we also felt that it was important to recognize that once the conditions of trust and interoperability existed, there will be entities that will be exchanging and will identify that there may be a technical requirement, there may be a policy that works in, for them, as they're doing their exchange, and they may want to move that, use that as part of their process within their sub-community, whether it'd be a state HIE, whether it'd be a community, a nationwide group of entities that are exchanging.

The option of that particular specification or policy may or may not have implications for other entities that are doing exchange. It may reduce competition. It may create barriers to others who are doing that exchange. We felt that that needs to be identified, discussed, and resolved. That some of that can be done without going to setting up a federal, going through a federal process of actually setting a rule or changing a rule. Some of that may require that that be identified and then shared with the Office of the National Coordinator for further action. That was the role that we were seeing this to do, to identify and monitor implementation, and to make recommendations. The second role was sharing and providing a means for input that would then go to the federal government and obviously be reviewed by the FACA bodies. It is, as you mentioned, a little bit of morphous, but it reflects the character of where we are right now in the process of exchange.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Other questions or comments? Yes, Deven.

Deven McGraw - Center for Democracy & Technology – Director
Yes. I have a similar question about the description of the role of the NGO or the NGOs. It's sort of, if what we're doing is establishing a more robust advisory process for gathering recommendations and reporting them into ONC, I'm not opposed to that, but I just want to be clear that that's what we're doing, and not necessarily vesting a private organization with sort of greater governance authority like the ability to wave conditions of participation or to decide policy or to have a more formal oversight role over implementation. Then along those lines, who do we envision being the validation entity, and who supervises them and has oversight of them, and who do they directly report to?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I think there was clear concern expressed in the workgroup about creating a nongovernmental entity that could make decisions that ought to be made by the federal government. I think that's the reason why you see the recommendation the way it is. The validation entity would be, could be any number of forms. We're seeing an overarching validation authority that may conduct a validation themselves. They may choose to delegate that validation and may identify a certain piece of that. For instance, it may be that,

as part of a process, and I believe that's coming up in the privacy and security tiger team, they're talking about a way to validate that they're engaged in a certain level of practices that protect the privacy and secure the data.

It may be the role of the validation process not to redo that, but to say, yes, you've gotten that level of achievement through whatever mechanism that exists there. There are other areas where the technical components of that exchange need to be validated. It's not clear at this point, as we move forward, whether or not that's something that can be done through a certification process. It may be done through some sort of accreditation of the entity that's doing exchange.

The first step will be for the Office of the National Coordinator at the federal level to identify the criteria for validation. Then the validation authority, which would be a nongovernmental entity, which would have delegated authority from the Office of the National Coordinator to identify, now how are we going to achieve that? What pieces of that might be better done by a separate entity or currently existing entity so that there are multiple pathways to validation? So that's kind of how it starts to build down. Building an infrastructure that says diverse is the ways that we believe exchange will go with the goal of trying to minimize duplication, minimize the amount of burden that exists on entities that are looking to exchange.

Deven McGraw - Center for Democracy & Technology – Director
Yes, I get that, and you're right, as we'll see this afternoon. We do have some recommendations that get to finding a way to accredit. You could substitute the term validate and making sure that entities that issue credentials for exchange, for example, are doing it in the appropriate way. But I guess I just want to push a little bit just so that I'm clear. The NGOs are recommenders and not validators, or did you not get to that piece? I see in here some pretty clear message that the role of the NGO is as either one recommending body or a set of recommending body or set of recommending bodies, but not necessarily setting policy, implementing policy, or overseeing policy in some sort of validating role.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
You actually asked two questions.

Deven McGraw - Center for Democracy & Technology – Director
Feel free to answer them both.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Let me parse this out. I'm a small practice in Anna, Illinois, a small town in southern Illinois. If I want to exchange, there's no HIE that I have to exchange. I want to be able to exchange. I would identify a validation entity that's appropriate for my type of practice, and they would apply the validation criteria that have been identified by the federal government, and they would issue me a certificate or a notice of compliance, and then I can then participate in this environment of the Nationwide Health Information Network, as we've described earlier. That is actually issuing a delegated authority to issue a validation based upon the policies and the procedures and the conditions that are established at the federal level. So yes, I do believe that the validation entities, we need to be able to say yes, you've done that. And we would not want to have that entity, take that, yes, you've done that, and then have to go to the federal government and say, okay, now issue my validation.

Deven McGraw - Center for Democracy & Technology – Director
Who chooses the validation entities?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
The initial process would be the Office of the National Coordinator picking the validation overarching body. That body may say, yes, we can do that, depending upon who selected what they are. They may identify that certain entities can also do that. So we're looking at an interconnected structure depending upon what experience tells us. But it would be a nongovernmental entity with approval of the Office of the National Coordinator would say, okay, we've now looked at it. We want to look at a validation entity for rural practices because we're not really good at that. We've identified that there might be organizations

that actually go out to rural practices and could conduct that kind of evaluation. At that point, that authority might be further delegated with the approval of the federal government.

David Blumenthal – Department of HHS – National Coordinator for Health IT
I think Paul Egerman was the next in line.

Paul Egerman – Software Entrepreneur
Thank you, John, for the presentation. That was absolutely fascinating. This was great. I have a couple questions. First, I have a question about continuing on this validation process. It occurs to me, as I think about the NHIN or NW-HIN, that there will be some participants that are sort of outside the scope of ONC, so you consider like independent laboratories or perhaps retail pharmacies, and so my question is, how does this entire validation process work for those entities? To what extent is ONC layering on requirements onto those organizations that may already exist from other federal agencies or maybe even from state laws?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I think that really gets back to some of the question that was being asked by Deven, which is that, first of all, ONC sets the conditions of trust and interoperability, and then the criteria for validation that are based upon those conditions of trust and interoperability. Participation in this environment of policies, procedures, and standards that we call the Nationwide Health Information Network is strongly encouraged and incentivized by the federal government, but is not required. Laboratories in this particular example may want to participate, at which point there may be an entity that takes into account, are they meeting the CLIA requirements? Are they meeting state requirements on labs? Are they licensed, as seems appropriate? Then this entity may say, since we're already in the labs doing this, we're already engaged in the lab, so our organization wants there to be a validation entity for clinical labs.

That then goes to the overarching validation body and discussion with the federal government to say, you know, that might make sense. Then authority would be delegated to what that entity might be. But the emphasis is that participation is voluntary, though preferred, and that adherence to the conditions of trust and interoperability are basically the payment of the freight in order to participate in this environment is that you have to agree to help create the environment of trust and interoperability.

Paul Egerman – Software Entrepreneur
This afternoon, we're going to hear a presentation from one of the workgroups about enterprise provider level directory, in other words, basically a directory of enterprises for interoperability. Does this validation entity interrelate with that enterprise directory? In other words, would the validation process be a basis as to whether or not the entity can be listed in the directory?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
We did not address that specifically, but if the character of the directory are to include those entities that are participating in the Nationwide Health Information Network, then one would think that they would need to be validated to be listed in that directory. Now I'm just saying that off the cuff. It may be that the directory is set up in such a way that it identifies every physician that's in the nationwide databank. There may be an entry that would say these physicians are participating in a validated network, and these physicians aren't. That really gets more to the structure of the registry than it does to the issue of validation.

Paul Egerman – Software Entrepreneur
Yes. The directory is not an individual clinician directory. It's a directory of entities, of organizations. It would seem to me, it would be ideally suited to relate that concept with your validation concept. That if you validate somebody, then they can be a member. They can be somehow listed in this directory as participating in NHIN, and it also could relate to how you do governance, which is if you want to terminate membership, you could remove them from the directory, and that validation entity might be like what Micky Tripathi is going to call the registrars, the people who decide who is able to be listed in the directory.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I think what I'm suggesting is that the committee— I think our workgroup would say that the validation is a tool that could be used for the directory. We did not specifically address how that directory should be set up and how they would decide.

Paul Egerman – Software Entrepreneur
Great. Thank you.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Paul?

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Thanks, John, very much. Clearly, in the abstract, there are a lot of soporific elements of discussion of this topic, but I think the minute you start wanting to do this, it's a real wake up call, and so all the things that you talked about were very important.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Nice touch, Paul.

Deven McGraw - Center for Democracy & Technology – Director
You got everybody scrambling for the dictionary, Paul.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
At the state level, I participated in the state, the California State eHealth Advisory Board, and these kinds of the clear enumeration you had of these topics have been very helpful and, furthermore, having such an entity that would lay out these attributes would be extraordinarily helpful, and I'm sure that's why Dr. Blumenthal asked this workgroup to be formed. Practically, to start the exchange going, we're signing up for a vendor essentially hosted exchange mechanism. They don't really have conditions of trust and interoperability like you describe, and I hope that we can actively become compliant with those attributes.

You've enumerated a number of key roles. It's the, what is it, the conditions of trust and interoperability, the criteria, the who validates and who enforces it. We've talked about a number of entities, and so did you have in mind? What would you say is a minimalist structure for being able to carry this out? Multiple times you talked about the burden that we'd all have to be certified for the EHR and the PHR, etc. What would be the minimalist structure to sort of carry out these roles, do you think, not that that's what the group would recommend, but is there a way to put it in a small number of boxes as possible?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I think probably the smallest box, we probably would all agree that there needs to be a federal role. Thank you, David.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Take it or leave it.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I think the smallest box for the validation function would be a single validation entity, and that's on size. I'm going to hedge. I'm not sure that that would be the most effective because that would tend to allow there to be duplication with current validation pieces, if that's not clearly done the right way. The single entity could recognize multiple pathways to validation, which could facilitate that. But if you don't give them the ability to do a little bit of branching out, you may create barriers that you don't want, but that would be the smallest. Then the third entity, which is that nongovernmental role, I think that there is a bit of concern that once you start putting that into the rulemaking process and the FACA process, it becomes frozen. So you could probably do the federal role and the validation role early, and then the nongovernmental role later, but I think that we would identify, as we get more experience, that we need to have something that plays that role that has the flexibility that a nongovernmental entity could have.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Can you combine the enforcement with one of the other boxes?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Yes, with the nongovernmental role box, the implementation role could be combined. In fact, I don't know remember if it was in this slide deck, but we did raise that in some of our earlier work, and that may have been left out. One of the questions is, could there be a single entity for that? The answer would be yes.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Charles?

Charles Kennedy – WellPoint – VP for Health IT
John, thank you for the presentation, although I have to admit I'm still trying to get it straight in my head. One of the things that might help me is, very clearly you've laid out a governmental role, a nongovernmental role, a validation role. But could you talk a little bit about, did the committee take a process view? In other words, maybe using e-prescribing as an example, there are data sources, retail pharmacy, PBMs. There's a network, SureScripts, RelayHealth. There are EMR vendors who present the data to the physician.

Did the governance committee look at kind of the span of control that you would need to effectively government more of an end-to-end process view? Then the second question is, how would the validation role interact with the EMR certification process, if at all?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I'm going to take the last one because it's the easiest, and that's where our recommendation is to leverage currently existing processes, so if an entity is using a certified electronic health record that meets the criteria and the meaningful use criteria, there would be no need to validate that component of it, so the validation process may be ….

Charles Kennedy – WellPoint – VP for Health IT
You'd just check the box and …?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Check the box and move on.

Charles Kennedy – WellPoint – VP for Health IT
Okay.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
The other issue of end-to-end fits in with the concept that we're really talking about a governance of governances, and that it may be that within a community or within a state that there's a statewide HIE that would—that the validation process would include the fact that they are validating the fact that their members are exchanging an environment that adheres to protection of privacy and security that are meeting the technical requirements for exchange. I think that's how we deal with that the processes of not trying to get the governance so granular that it's going to be dealing with how labs participate or other players.

Charles Kennedy – WellPoint – VP for Health IT
So I should think of this more as a macro process and then, underneath it, more the granularity would be left to the local HIEs.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Right, and it's the issue that we raised about, now what do you do if a community that's using direct, how do they interact with other entities that are playing that governance role? That's where we think this nongovernmental entity can play a role is giving them an environment where those kinds of conversations can occur.

Charles Kennedy – WellPoint – VP for Health IT
Okay, and just to conclude this train of thought, so again, using e-prescribing as an example, if we got into a situation, let's say, where we found the medication reconciliation function wasn't being used at a meaningful rate by physicians, and that was an issue that governance needed to deal with, that would be handled more at a state HIE or lower level is what I'm understanding.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Let me deal with that. It may be that within Missouri that it's not being done, in which case that would be a governance issue within the Missouri exchange. It may be that we're looking across the nation and saying that's not being done very well anywhere, at which point it becomes a federal role, and that involves the conditions of trust and interoperability. So there may be guidance at the federal level saying we need to modify how we're doing this, how the reconciliation process is going. That is how I think those issues would be addressed.

David Blumenthal – Department of HHS – National Coordinator for Health IT
David?

David Bates - Brigham and Women's Hospital - Chief, Div. Internal Medicine
Thanks, John, and thanks to this committee for working with really tough problems, and there's an awful lot here to assimilate, and I haven't assimilated it, so I just want to identify three or four things that I think I will want to hear more about and think more about to try to get to an understanding and resolution on this. Like Paul, I'm working on the California state designated entity, so we are wrestling with many of these issues within one large, regional entity. We have taken the approach of standing up the provider, the entity registry as a platform to do some of this certification or validation activity, and so we're wrestling with what are the criteria and so on. It's very difficult work, and we don't know the right answers, and so one of my conclusions from that is, does anyone know the right answers? Is there anybody yet capable of standing up and saying, here is the platform, or do we need more of a laboratory model in which the outer guardrails of risk are defined? But there's a lot of latitude to do development and innovation on how this should work because we don't know yet.

I'm ambivalent, frankly, about the right way to proceed, and I'm closer to the state level, so a couple concerns I have. One is this healthcare exceptionalism problem. There are many, many other markets, many, many other information exchange platforms that don't have this layer of federal and NGO regulation and oversight, or they bound it very carefully, so there's a layer of top level policy that I personally think we do need governance for, and there's a lot of stuff underneath that that hopefully can be more dynamic and less micromanaged, if you like. I'm more worried about where it is. I think we need to, and the process we're doing here needs to justify for what data, in what ways, for what transactions is healthcare exceptional and, therefore, it needs a different mechanism than other markets and information environments ecosystems use.

I'm concerned about the states. They're very minimally referenced in the model we've talked about today, and they're obviously funded and standing up these fairly elaborate enterprises, so I think being real clear on what the state rule is, as distinct from the federal role, will be very important guidance to them and to the markets. I feel like there are some principles that I have in my head that are not either supported or disputed in the governance work so far, and so I think a little more clarity about what principles are guiding our discussion would be really helpful, so the kinds of things I'm thinking of are things like least intrusive, top down regulation as a principle or not. But to articulate what is the premise of the regulatory approach that is implied by this infrastructure. An outcomes oriented approach is always one that I'd prefer where we're not necessarily micro – dictating the processes of data management, for example, but we're holding people accountable for the outcomes of privacy, security, use of data that are public policy relevant. I think that makes it somewhat easier to enforce.

On that front, similar to the exceptional one, I wonder where does this infrastructure become necessary, as distinct from the world of faxes and phones and other data handling. That is, we're addressing, we're responding to a set of risks that we're aware of in this IT enabled environment that are real, but there are

many risks in the non-IT environment that we haven't built this kind of infrastructure for, so I want to understand that. Particularly, I'm concerned about the discussions we've had in the past, but a lot of privacy and security risks are actually about human behavior, not about technical interfaces and processes.

We don't anticipate an environment where, for example, the validation enterprise is going to go inspect doctors' offices in Illinois, whereas that may be where a lot of the risk is that manifests in data information exchange, so I want to understand what that principle is that we're anticipating governing that kind of work. So I think that's my list at the moment. There's a series of, I guess they're contextual things, and maybe I missed too much of the discussion to appreciate that we have them, but if we do have those contextual things well understood, I think we need to document them in support of how we proceed with the recommendations.

David Lansky – Pacific Business Group on Health – President & CEO
I think the ideas that you listed as principles, we did list our nine principles. I went into a fair bit of detail when I was here last month. I think most of the ideas that you raised were included in more of the detail, the devolution to the local level for decision-making, fostering innovation, and identifying barriers, monitoring the outputs of what the governance process is doing. So I think that they are there, or you didn't raise one that we haven't looked at.

Going to the issue of, and I think it's really critical to get to, as a system of governance of governances and, I think, a system of validation of governances, the clearest one is where there's an HIE that's in existence. And that is that we would see this process validating that HIE, and that we would not want to get to the point of validating individual clinician offices. That's pretty clear. If there is a state level, the interplay between the federal and state regulations on these sorts of issues are going to be complex. They're going to be more complex.

But the longer it takes for there to be conditions of trust and interoperability established at the federal level, the more likely it is that there's going to be a state governance mechanism that will have significant variance. By creating the state model, what people in states, at least in my experience, tend to do is they build off of the federal model rather than trying to reinvent it. So that's, I think, going to be a critical component of coordination with the states.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Chris?

Christine Bechtel - National Partnership for Women & Families – VP
First of all, John, I want to say thank you to you and to the ONC staff who have done a phenomenal job really fogging through some technical, complex stuff, and I appreciate your leadership on that. Coming back to the discussion of the NGO and the questions that Deven raised, in my understanding, this is an entity that would have an impact certainly on the market, but also in some areas of policies. So the slides talk about delegated authority from ONC, authority for results to be binding through authorization, denial, revoke, etc., the ability to raise the need for potential policy changes to ONC, which I think is an important role. There are references to its recommendations carrying significant weight with ONC, and the, of course, any time you have an entity who is interpreting the application of a policy. Even when that policy is set by someone else, there's of course an opportunity for impact there.

So I don't dispute that these important attributes by any stretch, but I was one of the folks on the workgroup that was not fully comfortable with the idea that this would be a public/private entity or an NGO, whether that's an existing entity or one that stands up de novo. I wanted to raise some issues because I think, given the impact that this entity could have, it does need to be trusted. They can clearly influence, as a FACA or other entities could, the conditions of trust and interoperability. I raised this issue previously this morning with you and Mary Jo, so you're not surprised by this, and I appreciate you acknowledging some of the affiliations of the workgroup members in advance.

But I want, in the interest of openness and transparency, acknowledge the fact that I think one of the entities that is probably widely considered to be at least a candidate for this role is the National eHealth Collaborative. I received a newsletter just last night from the collaborative that made clear to me that there are a number of folks on the workgroup that have either very strong leadership ties or some other relationships to that organization. Had this decision in the workgroup, as I mentioned, been one that was unanimous, that everybody was comfortable with, maybe this wouldn't be an issue. But given that this is about governance, and that that wasn't a unanimous decision, and having had that discussion and arrived at this potential recommendation not really understanding the fact that some of the workgroup members are on NEHEC forward and have other various roles, the coordinating committee clearly has a relationship with NEHEC that I don't understand.

I just know that this newsletter came out signed by the chair of the coordinating committee and from NEHEC's e-mail. I just want to be open and transparent about that, and I want to be clear that I'm absolutely not questioning anybody's integrity personally. I believe all the workgroup members have their hearts in the right place, and they're some of the smartest people that I know, but I think this has raised a real issue for me, and I'm having trouble because I think, A, the policy committee needs to know that when it's considering these recommendations. While I'm very supportive of many of the other recommendations, this one I just have some heartburn about allowing it to go forward simply on optics alone.

I think it's absolutely possible that if we were to reconvene with a broader set and have an open discussion, we may very well arrive at the exact same recommendation because I understand the challenges of a FACA in an implementation role. That doesn't quite work. But I think we ought to look at a fuller set of options and have an open and transparent discussion about that, and a process that might generate some more agreement. But on optics alone, if we want this body to be successful, then I have a concern about that particular recommendation that I wanted to flag.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Thank you for that. Let me just respond with a couple of things. First of all, in this report, I noted a number of times that there were members on the committee who felt that it should be a FACA as opposed to a nongovernmental entity. All of these discussions were held in an open forum. The issue of a nongovernmental entity is one that has been on the plate of the group. But given all of that, this is not a decision that our workgroup is making. We're making a recommendation to the policy committee. The policy committee is the entity that then makes the recommendations to the Office of the National Coordinator.

The role of that particular body, and I think that there are some fairly strong discussions about that. We had no discussions about any particular entity playing that role, and I might actually disagree with you on what entity might play that role or whether an entity that currently exists could play that role. But I think it's going to be the job of the ONC when they start to develop the rules to look at, okay, as you look at what this role might be and who is going to play it, who might be eligible to do that? I just don't think that there's any clarity on that, nor is there direction in our recommendation that would provide clarity on specifically identifying any currently existing entity as being able to play that role.

Christine Bechtel - National Partnership for Women & Families – VP
I really appreciate your reaction and your response to that, and I know we had a conversation ahead of time. I'm simply saying that regardless of what may or may not happen, those preferences, affiliations, and relationships have the potential to influence this recommendation, and that we should have at least disclosed them during the discussions of the workgroup. I absolutely understand the process that neither the workgroup, nor the policy committee makes any decision. But as a member of the policy committee who is going to be asked presumably today to support these recommendations, I want to signal that for this particular one, I'm uncomfortable at this point.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Thank you, Christine. Adam?

Adam Clark – FasterCures – Director, Scientific & Federal Affairs
Thank you, John. I'm going to hopefully break it down a little bit so that I can better understand at least from my angle what this network would be. You mentioned emphasizing being inclusive of consumers, and just for clarity, when you say that, are you using the word consumer talking about patients and caregivers actually entering into this network and participating into this network and the exchange of information or verifying that I'm me, getting I'm records, sending my records somewhere else, or are you using the term consumer in a different light there?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
As we envisioned the environment of exchange, consumers get information in this environment through a number of ways. They are going to get information from perhaps a vendor of a personal health record, and part of the conditions of trust and interoperability and how a vendor of a personal health record or a manager of a personal health record would be able to exchange information with a provider who may hold part of that information would be part of the validation process. I don't think that we have envisioned that an individual consumer would be an entity within this exchange. So they may get it through a portal. They may get it through some other mechanism.

We did not address or even discuss the issue of whether, okay, could you have a group of consumers who would get together, and they want to share their health information like patients like me. Those are probably the kinds of issues that need to be addressed at a more granular level than what the structure should be. But what we felt was important is that when policy is being set, that consumers should be at the table and that we believe that consumers can participate in a meaningful way in giving advice about how that policy should be framed.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Art?

Art Davidson - Public Health Informatics at Denver Public Health – Director
Yes. Thank you, John, and for the work that the workgroup has done. I'd like to go back to your example of a Paducah to Poughkeepsie. You have these nine principles here. The conditions of trust and interoperability are established, at least on one of the slides, the potential ones. How would that be different if it were from Paducah to Peoria, and is this really about a baseline set of conditions of trust and interoperability? I'm trying to understand a little more about this validation and how you get the provider you described in some corner of Illinois.

The HIE of Illinois is involved in this exchange within the state. Wouldn't we expect that these conditions and principles exist for the HIE in Illinois and that this is now setting the floor? When would it be different than this floor?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
One of the things that we learned as part of our information gathering, there are, I believe, and I can't remember if it's North Carolina or South Carolina. There's actually a signatory to the DURSA that represents a small group, and that's because they wanted to exchange, and they didn't have an HIE that they wanted to participate in or could participate in.

Looking at the range of potential ways that exchange can occur, basically I think that if it's going to be between Paducah, let's say Anna and Peoria because they're both within the same state, and assuming that there's a state HIE, they're going to exchange within that HIE. The governance mechanism of that HIE is going to determine the rules of the road. They're going to be applying the conditions of trust and interoperability based upon their accreditation, their validation. So the validation process would validate that exchange and not the members of that exchange. If I'm in Anna, and I want to share information with a provider in Peoria, because of the fact we're in the same exchange, I know that they're using the same environment of trust that I'm used to.

The question is, how do you then do that with somebody, and that's the reason whey the example of going to Poughkeepsie because I don't know the person in Poughkeepsie. My exchange may know their

exchange, in which case the validation, the environment of trust and interoperability, the environment that's created by the standards and policies says that if I'm going to exchange information with this individual, it's going through my exchange. I trust my exchange. My exchange, and I'll trust the exchange in New York State. So I can exchange with this guy or hospital in Poughkeepsie. What we did was try to also think about whether or not the people on both ends may not be part of that exchange, and at least provide a way to participate.

Art Davidson - Public Health Informatics at Denver Public Health – Director
So you're saying that the people at the end there may not be abiding by these nine principles, and those same conditions of trust and interoperability that govern the NW-HIN?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
If they're participating in NW-HIN, they either—because the two entities are exchanging, may know that there's an environment of trust and interoperability because they have both been validated, or they're participating in a validated entity of exchange. That entity of exchange may be an HIE. So if I'm in a state in California, and I'm exchanging information with somebody from San Francisco to Los Angeles, we're all in the same exchange. No one stops and says, okay, I'm going to send information to Dr. Jones. Can I do that? It's because I know that what I had to do in order to become a participant, and I'm assuming that other guy had to do the same thing.

The environment we're creating at the national levels says that when you do that, because you see that they have been validated, whether it's participating in exchange or validated as a separate entity, that they are doing what I had to do, and so I know I can trust them to get my information that I'm sending. They're going to protect the privacy. They're going to hold it securely, and that when we do the interoperability, the exchange, that it will be some measure of interoperability.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Marc?

Marc Probst – Intermountain Healthcare – CIO
Thank you. John, thanks. I guess my question comes down to a couple of terms, and that's validation and certification. I'm not sure if I understand the difference, and if validation is something additional and new. I guess the example that's going through my head is I want to go get my car inspected, and when I do that, I want to be able to drive on surface roads and actually get on federally funded highways. No, I've had that done once, and I can do all these things. Is the governance here going to be an additional? Is there another validating body or certifying body that's going to do the NHIN, or is this all encompassed in certification?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
The answer is that we do see this as being a different body, but that there are, and I can get this wrong, and this will explain why we use this term. So you certify an entity, and you accredit, and you certify a tool, and you accredit an entity. But when you're trying to describe what you're doing and saying that an individual using a certified electronic health record, which would probably be one of the conditions of trust and interoperability, they are exchanging in a way that's consistent with the conditions of trust and interoperability related to privacy and security, which may be an accreditation. We can put those together into a single term of validation.

We think it would be very cumbersome for people to have to go around and get merit badges. I've got my privacy merit badge. I've got my interoperability merit badge. We think that pulling that together into a single process, that would be called validation. Again, it may be a single entity, which could be a small practice and very rare of circumstances, but more than likely we're talking about the exchanges themselves, whether that be a community based exchange, a statewide exchange, or a multistate exchange.

Marc Probst – Intermountain Healthcare – CIO
Thanks.

David Blumenthal – Department of HHS – National Coordinator for Health IT
I do want to point out though that if you were going to – if the Office of the National Coordinator were going to recognize validating groups, it would do so on a competitive basis, and certifying bodies couldn't compete to also be validators. They might have a department of validation and a department of certification. But the groups that have by now qualified to be temporary certification bodies could say we've got this, and could put together an application to compete and win. So it's not required that they be separate. As a matter of fact, we couldn't unless we had very good reason to exclude them from competing.

A permanent certification process, which is still a final rule for which we're hopeful will be out soon, and in the NPRM, contemplated an accreditation process for certifying bodies. So there are many, and so ONC would picking accreditors for certifiers. So there are going to be a whole series of entities, which could form the nidus for validation or the choice of validating entities, and it would be a premium, I think, and placed on not creating new bodies for the sake of creating new bodies.

Marc Probst – Intermountain Healthcare – CIO
Who would be the enforcement body overseeing these varying levels of certification and validation?

David Blumenthal – Department of HHS – National Coordinator for Health IT
I'm not reporting here.

Marc Probst – Intermountain Healthcare – CIO
Sorry. You're the last one who spoke.

David Blumenthal – Department of HHS – National Coordinator for Health IT
There are reporters, and then there are listeners.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
If I can just give an analogy, no one has the right to drive a car. In order to drive a car, you need to have a license, a driver's license, and that's by demonstrating at some point that you meet certain criteria and certain skills. If your right foot has a high degree of nonferrous metal, and you get stopped multiple times for going too fast, then you lose that license to drive.

That's the kind of enforcement. I think we have to be careful. We're not talking about fines. We're talking about an environment of trust and interoperability. How do we know those who volunteer to participate, I'll bet with incentives, are following the rules of the road. If they don't follow the rules of the road, then the enforcement would be to ideally, okay, let's come to an understanding. You're not following the rules of the road. Let's get a plan of correction, and let's implement that. If not, then the ultimate enforcement is to say that you really can't say that you're participating in this environment of trust and interoperability.

David Blumenthal – Department of HHS – National Coordinator for Health IT
I'm trying to keep track of who is who. Who is in what order here? How about Paul? I think Paul went up before David went up again.

Paul Egerman – Software Entrepreneur
I wanted to follow up on a comment that David Lansky made about what he called healthcare exceptionalism. I think about why the healthcare environment is necessarily different than so many other environments. When I think about the Internet, I think that one of the reasons why the Internet succeeds as well as it does is because individual sites are allowed to fail. And think a lot of people don't think about it that way, but we all know that when you look at any individual Internet site, any site on the Web, there's no way, unless you know something about the site, there's no way to know I the information from that site is accurate. In fact, we all know that there's a lot of inaccurate information that's available on the Web, so you have some sites that you trust, and there's some sites you look at skeptically. So my question is, as we think about your validation process and your governance process, have you considered a process by

which you limit your validation to very simply technical interoperability and also technical security provisions, but that's all, and you don't consider things like the issue that Charles raised as to whether or not somebody keeps their medications list up to date or whether or not they're really abiding by privacy rules because those policies, because those are much harder issues? But simply limit yourself to the technical aspects.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
One of the things that I've learned in this particular field, and this may apply to healthcare exceptionalism, although that's not necessarily always the case, and that is that the people in this country are very concerned about how their health information is used, and I was involved. I chaired the NCVHS when we went through the privacy rules under HIPAA. I can tell you that those rules brought home to me that there was a significant portion of this country that if they aren't assured of their privacy will not participate. The implications of that are overwhelming. You will have people who will forego care because they're concerned about their privacy. You have people who will not get their medications because they're concerned about privacy. There are all sorts of significant ramifications that I don't think exist in other fields to the same extent.

One of the issues that we addressed early, and we've discussed at our report last month, and we've been living this for the last month, so I wouldn't expect you to remember it the way that we do, is that we think that part of the monitoring process is an ongoing balance of risk versus impact. The ideal private protection of privacy is to write everything on a piece of paper that I then put into a safe. That is not the best thing for assuring that every time an individual meets with their caregiver that they can make the right decision with the right information, and so we're always having to balance those two.

I think it's a dynamic balance, particularly as we learn from experience, and the technology, and the lessons learned when exchange occur. But we really have to beware that this system of health information exchange can only exist if there's confidence by both the public, as well as the providers in it. That the fact that what we learned when we were conducting those hearings, now I guess it's been 10, 15 years ago, is that the issue is less technical than based upon the policies and procedures that occur. It is as true with paper as it is in the electronic media that if you see a patient, and you leave all your charts sitting out in front of them and paper, that's not protecting the privacy of your patients. So that really is something that is a critical component of health and healthcare, and I think has to be reflected in the rules of the road for exchange of health information.

Paul Egerman – Software Entrepreneur
I understand those issues, although I do think you're establishing a structure where, in effective, there's confidence in every participant in the NHIN or the NW-HIN, and that's the basic premise that I'm suggesting that that's a suggestion that you reconsider. That you could have a situation where the patient's caregiver, the patient's individual physician makes decisions as to which entities information is exchanged with. As a result, you don't necessarily need to have confidence in absolutely every participant.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
If I could just respond to that, I can tell you that having practiced as an emergency physician, and having a patient come in with a scar that basically goes from their mid chest all the way down to across their abdomen. You ask them what happened, and they said I had surgery because the doctor told me I needed it. You look for trusted sources of information. You learn that you can't just ask a family member. You have to try to get a hold of their record. Every clinician recognizes that if they let go of information because they said they were a doctor, and they called for it, that creates problems. So now how do I, as a physician in Poughkeepsie, who gets a message that I need the medical record for somebody in Paducah, how do I know I can actually send that in a way that's both safe for my patient and safe for me? And that's the environment of trust that we're needing to create. We need to create an environment of trust or exchange will not happen.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Neil?

Neil Calman - Institute for Family Health - President & Cofounder

This is incredible work, and I have trouble understanding it all. I'll admit that to start, which is why although my name keeps appearing on the screen as being part of this workgroup, I graciously resigned after the second meeting realizing that I was only following about 10% of what was going on, so forgive me if these questions are not fully informed.

But it seems to me, like in slide seven, I sort of got immediately sort of had a problem. You define like what's being governed by the people who follow, who decide that they're going to follow the rules. So to use the road analogy, I think you can get the license. It gives you an opportunity drive on the road, but what if you decide to take your four-wheel-drive and drive across everybody's front lawn? What happens to the people who decide they're not going to use—it says, when is exchange not considered part of the nationwide network? It's when people assert that they're not part of the nationwide network.

I start thinking, so there's this whole other part of exchange that's going to go on that we're not even claiming that we can govern through this, and I'm okay with that. But it's just that people need to know that. That we're actually talking about governing people that are sort of choosing to participate in this one mode of exchange, and maybe that's a good thing because it enables people to do things outside of this structure if that's what makes sense.

But the other thing that bothers me, I guess even more than that, is that I think we're making false promises to people who are going to depend on us, this mechanism, for sort of trust because, as David Lansky said before, as I've said before as well, the real risks take place at the provider level. I don't think we have a mechanism other than the ones that we already have in place, HIPAA and other things that really are going to enable us to assure that when the information gets into the hands of somebody else that's going to be used appropriately, and so I think we can create. It's kind of like I remember in math. You're multiplying two numbers to eight decimal places, but the third number only has one decimal place, and it's only as good as one decimal place number. You can't make it more exact.

So we're creating this whole mechanism about trust and everything, but the real risks exist at levels that we're not even touching or discussing, which is really what's happening when the information gets to these entities, and also I think what's happening outside of the structures. So I don't know how to deal with those things, but those are just my observations. It doesn't negate the work that we're doing to create this mechanism. It's just that I think we need to also spend a lot of time and attention on the other pieces. Otherwise we're going to create this mechanism of trust and the distrust is still going to come from the public because we won't have covered those other bases.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

I think the issue is, first of all, Amen, but—and the but is that we operate in this country under a system of laws, and governmental officials can only get engaged in environments where the legislative body gives them authority. In this particular instance, there is no authority to say that if you're going to exchange data, you have to do it in a certain way. There is authority to say that if you're going to exchange data in this environment, that you have to meet these conditions of trust and interoperability. The first way that this started was under the DURSA where you had individuals who had some contractural or grant arrangement with the federal government who began to exchange. Under the coordinating committee, the rules of the road were established.

Now at some point patient advocacy organizations are going to say, if you're concerned about privacy, if you're concerned about these issues, then you need to ask your doc or ask your hospital, are they either verified directly or as part of validated or part of the validated entity. In other words, do they exchange? Can you show me that there's some proof that you're actually protecting my privacy?

At that point, I believe that the other thing that we believe a lot in this country that the market will play a role, and people will sign up because they believe that that's important for them to enable to continue to have their practice. But we do have restrictions on who can be mandated to participate, and that does create venues for exchange that could cast incorrect perceptions about what health information exchange

is about. I think that would be a bad thing because then people would go into not exchanging data, and the kinds of decisions that people want to make with their caregivers using all the information that's necessary to make those decisions won't be possible.

David Blumenthal – Department of HHS – National Coordinator for Health IT
David?

David Bates - Brigham and Women's Hospital - Chief, Div. Internal Medicine
I've been quite for many of the same reasons that Neil has. It's still hard for me to follow this whole area. One thing I wondered, I wanted to ask you if it's come up is a discussion of conformancy. I don't want to introduce a new term, but obviously a lot of the discussion about validation. If there's not conformance though, I'm still struggling with how this will actually work at the ground floor level, especially if there's not an HIE involved. Sometimes there will be an HIE involved, and I understand that. But was there a discussion about conformance, and perhaps what needs to be done to promote the development of organizations that would do some conformance testing?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I'm sorry. I'm not sure how you mean the term conformance.

David Bates - Brigham and Women's Hospital - Chief, Div. Internal Medicine
Let me give you an example. When data is exchanged, often it's hard for one side to understand the other. And for example, even when an HL-7 message is exchanged, that doesn't guarantee that things will work out.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I think that's where the concept of the conditions of trust, which are privacy and security, and interoperability, which is what gets sent is not only received, but it's understandable in the context in which it was sent. Those are where those standards would be applied, and that part of the validation process, and it may be by accepting certain certifications that have already been achieved, would say yes. They're adhering to these standards and technical standards of interoperability to insure that the message that was sent was the one that's received.

We think that those conditions of trust and interoperability, now the only thing where this gets a little bit fuzzy is that we don't know what all the right things are. We know that this cup and this one both hold water. So we need to have a mechanism that if that's the requirement is that they hold water that there are alternative paths to achieve the same level of compliance and interoperability, and we want to make sure that there's room to do that at this point.

David Blumenthal – Department of HHS – National Coordinator for Health IT
David Lansky is next, and then we'll go to Deven and Art. Actually, Jim Borland, I'll go to Jim after David.

David Lansky – Pacific Business Group on Health – President & CEO
On my first pass, I hadn't fully gotten my head around some of the governance issues that we're actually talking about, particularly the issue of this is the last couple of comments have surfaced again sort of the jurisdiction and authorities question. I know we had this exact discussion in California last week about the voluntary nature of participation and what happens to people who exchange information without going through having the blessing of, in this case, the state designated entity. If the state promulgates standards, that in terms raises the question of enforcement.

I think it would be useful for this discussion, at least for me to understand better, whether we anticipate this being essentially providing voluntary guidance and, if so, that's fine, or is it essentially moving toward a regulatory mechanism, and how does that play down through the different layers of jurisdiction and then ultimately enforcement? So it is a universal or a voluntary paradigm essentially?

Secondly, the role of public and private entities in the process, and you've articulated the NGO role and then the validation role, which I presume is largely private. I think, personally, at the top level of policy

development, I am uncomfortable with the private role, so I think what we've developed here with the FACA process and so on, and in the California model, something analogous that we've developed has been, I think, successful so far at the policy setting level. I think the slide materials were a little ambiguous about what's formal and what's informal and what's an overarching authority and what's an authority and so on. I think getting precision about that will be really important.

I am concerned in particular that we not pass the buck of governance, difficulty to an NGO or any other party. That the fundamental governance problems of who is represented at the table, how much influence they have, who they in turn are accountable to or represent in their day jobs, conflicts of interest, disclosures. Those are very, very gnarly problems, and we have to be extremely judicious in how we develop these proposals to acknowledge that this is a multibillion-dollar industry with a lot of stakeholders involved and affected. And so the governance problem, by saying an NGO will handle some aspect of this, to me only says what rules will we impose on an NGO to insure its transparency, accountability, fairness, and so on, which brings you back to a quasi public process.

In California, we actually had the experience of a very difficult engagement with the state government, who in turn was engaging with ONC over exactly what rules will govern the private sector after, which actually just became six months of more legal complexity and contracts and terms and bylaws. So I don't want us to trivialize the difficulty of handing off some of these functions to entities that don't operate under the explicit scrutiny of public sector oversight, which I think, at the top level, we need to retain.

David Blumenthal – Department of HHS – National Coordinator for Health IT
You don't have to respond to every comment, John.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I wish you had told me that earlier, but I actually do want, on this one. I think the issues of authority and so on, I think those are well taken, but I think it's really important to look at regulatory schemes. Those of you at this table may not know, but I was state health director in Illinois for 12.5 years, and so we had a number of regulatory schemes. The one that you think of most likely is the licensing of particular entities. Those aren't voluntary because if you look like a nursing home, you need to meet these requirements. They're very specific. If you in fact hold yourself out or provide nursing home care, then there are fines and penalties associated with doing that outside of having a license.

Our system of government has determined that there is a way that people can exchange in an environment of trust and interoperability that we're calling the Nationwide Health Information Network, and we can set the rules of the roads of people who participate, but we cannot say that everyone has to exchange in this way. There are other rules, HIPAA and others, that determine how you have to protect health information. You can do that, and you can actually exchange it. You can get in your car, and you can drive between Paducah and Poughkeepsie, and you can carry that, and you look in somebody's office, and you can say, okay. That looks safe. Here's the record. There are many other ways for this to occur, but we're trying to create an environment in which exchange can be facilitated, to facilitate interoperability, and that's based upon trust.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Let me go to Jim since he hasn't had a chance to ask a question yet.

Jim Borland – SSA – Special Advisor for Health IT, Office of the Commissioner
John, I too want to congratulate you and the workgroup on just an amazing job. I guess I'm fortunate in that I pretty much understood everything that you talked about. I'm not sure if I have a comment, a question or a comment. I'm thinking about interoperability and trust and validation and advice and counsel, and I'm looking at interoperability as something that can be truly validated. It either works or it doesn't. It gets to Paul's point.

I'm looking at security, which is a component of trust, and that's something that clearly can be validated. Both of those can be validated using existing validation means, and it's part of this certification process presumably. Privacy isn't something that can be validated, I don't think. I think it's something that's made

up. It's a fabric of laws and rules and regulations. But yet, we have mechanisms to validate that today in existing statutes like HIPAA. At the end of the day, I'm thinking that what the NHIN governance process does is it takes existing mechanisms and says if you subject yourself to those mechanisms and successfully demonstrate that you are in compliance with them, then you get the NHIN brand, which is, I think, an attempt to create kind of a UL listing for a healthcare provider, you know, a trust emblem that your provider is protecting your information and exchanging information according to the rules that are set at a national level or at a state level. Am I kind of getting this?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Yes.

David Blumenthal – Department of HHS – National Coordinator for Health IT
We'll go to Deven, and it's getting close to 12:15. Maybe we'll include Art, and then just before Deven's comment, we've got a set of recommendations in front of us, and this conversation has been very illuminating. I do want to preserve a minute or two to talk about what we're going to do next, so maybe after Deven, we'll go into that conversation.

Deven McGraw - Center for Democracy & Technology – Director
Yes, and I'll be brief. I'm with David Lansky on many of his points, including that I now have a more full understanding of what we're trying to do here, and I think my real heartburn comes with having a central validating authority that we think should be a private NGO body without a lot more clarity on the characteristics and attributes of this body. I get the multi-stakeholder part, but just putting consumers at the table doesn't necessarily guarantee when you've got multiple other stakeholders that you'll end up with a validation process that is actually fair and trusted by the public.

If I think of some of the nonprofit organizations that we have that provide some sort of delegated functions in our healthcare system, they sort of got to that point not automatically, but by building up trust over time. NQF comes to mind, for example, as an entity that we're coming to rely on increasingly to set policy, but it wasn't automatic. They had to build up the trust and show that they could be responsive to all of the stakeholder concerns, including consumers in the public, and they did so in a very deliberate way.

Having said that, and I do want to get to David's point about what do we do next. I'm extremely uncomfortable. I give you all a ton of credit for weighing into this, and I know that you have had intense amount of meetings. Our president, Leslie Harris, was able to participate in most of them, but not all of them because of the intensity of the schedule, so I know what that is like having been through the tiger team deliberations this summer, and a whole lot of work goes into it. So I hate to say it, but I don't feel like I can move forward on the recommendation of a central private validating authority without a lot more detail about what that would look like.

If I think about it in the Internet context, we do have a lot of sort of industry policing of itself on targeted behavioral advertising. For those of you who have been paying attention to the *Wall Street Journey* series recently, that has just not worked. Bringing consumers, requiring consumers to be at the table of private regulatory bodies is not a guarantee that the entity will act more in the public interest.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
If I could just make one slight correction—I understand your concern—I was involved early on in the National Quality Forum. It was created based upon a recommendation of a presidential commission, and it was designed specifically to play the role that it is, and it was structured in such a way to have those protections. I think that it has developed that trust because it was designed that way, and so I do have a belief that you can do that.

Deven McGraw - Center for Democracy & Technology – Director
I know NQF also made some major changes to its board structure in order to respond to some—within the last five years, to respond to some criticisms of some people who felt as though it wasn't actually operating in accordance. At any rate, I get that it was structured right from the get go, but I think there is, at least in my view, number one, yes. We do need more details when we structure this. But number two,

I think, until we do that, it's very hard. I know it's personally very hard for me to say, okay, we can go forward with this, that particular piece of the recommendation.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Do you want to make a short comment, Art?

Art Davidson - Public Health Informatics at Denver Public Health – Director
Very short, yes. Thank you for reminding us of your role in the state government. During the deliberations of the committee, of the workgroup, was there a specific role or did you define how states would be involved, states such as the state health authority that you were involved with, and how there would be delegation of authority to those states from this body, whether it be an NGO or the ONC? I didn't quite hear that in here, and I didn't see any of that on the slides. Maybe you could just quickly address that.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Sure. I think we started off with our hearing, we heard from the state of Minnesota, and they identified their mechanism of governance. We did take that into account. The difficulty of it is that most states right now are not engaged in regulating this. Most of them are engaged in facilitating the setting up of health information exchanges, and my gut feeling when I listen to the presentation for Minnesota and also a little bit about New York was, and they reacted a little bit negative to this, but a little bit of a sense of fear. I think that the environment of communication, and I'll just go to Kansas City. If you have different rules of the road on one side of the street because it's in Missouri and another side of the street because it's in Kansas, you're really setting ourselves up for a nightmare for providers that are multistate in character. So I think it's early enough that the federal government can play the leadership role without having to set a mandate to states. I believe that states will then follow in ways that will allow them to use their authority to build on to the federal platform rather than create their own.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Again, John, we've given you a lot of tough questions, but they're all offered with gratitude for the really seminal thinking that you and your panel have done, so hats off to you for the careful thought, identification of the gaps, identification of the issues, and making tough choices and coming forward with a set of recommendations. I think this discussion has been extremely educational. We know that there's at least one member who feels like he didn't understand things at the beginning, and now he understands more, so that's progress.

I think, every time I hear this discussed, something else clicks or falls into place, but I do think this discussion probably hasn't gotten us yet to the place where the policy committee feels comfortable voting on the recommendations you've put forward. I think that part of what we need to do maybe to set up the recommendations more clearly as choices or as sort of directional recommendations, and bring them back to the committee for discussion at that level. I think a lot of this discussion was about understanding what you were proposing. I think we may be in a better place now to actually discuss recommendations in a next meeting. Does that seem reasonable to people or not, or do people just want more detail and much more detail? Deven, you sound like you just want a lot more detail.

Deven McGraw - Center for Democracy & Technology – Director
Yes. I think if we're going to give, if we're going to say that there ought to be a central validation authority designated by ONC that's a private organization, I think I'd need to know a lot more detail about what that would look like before I could get comfortable with it. Now I understand from talking with John that they were under some time constraints, so I'd be interested also to hear from ONC staff about sort of what the time parameters are to be able to sort of try to nail some of this stuff down more.

David Blumenthal – Department of HHS – National Coordinator for Health IT
We would have very much liked to have recommendations, but it's clear that you all are not ready. We are not going to be ready to have them. I think the process of advancing the report and the recommendations has been enormously educational for everyone in this room, and also for ONC. And so there's been a great deal of value gained. We have to continue to move forward with thinking about this

process, the process of governance. But that will, that movement will proceed over months, and we have to get working on initial ideas for a regulation, but those ideas aren't going to be in stone any time soon, so I think there is time to come back and at least get from this committee directions.

There may be, for example, the question of do we need a governance entity at all or a governance mechanism, and what should the governance mechanism concern itself with? Should there be a validation process, whether it's federal or not, whether it's federal or private? If it were to be private, what should its characteristics be? That might be something we could reach agreement on. I think what I have in mind is framing the recommendations in a way that give us clearer choices to express views about then we have at the current time. Yes, Christine?

Christine Bechtel - National Partnership for Women & Families – VP
I want to actually support Deven … which is, I think there's Deven's suggestion, which is that there's actually a deeper dive around this body and its attributes, its board composition. Deven mentioned NQF, and NQF has a simple in their bylaws, they must have a simple majority of consumers and purchasers on their board. So some of the more detailed structural attributes of the organization that could create trust, there are general attributes around process in these recommendations. But I think that's actually a new piece. It's not just sort of explaining the choices. It's actually a new piece that I think is worthy.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Well, could we do this in a phased way then? Well, maybe we should take this up offline, but we could have the idea of a validation process, apart from how it's structured, has enormous implications. We might be able to get to agreement on that, even though we haven't got to agreement on what the precise characteristics ….

Christine Bechtel - National Partnership for Women & Families – VP
Who would do it?

David Blumenthal – Department of HHS – National Coordinator for Health IT
Yes.

Christine Bechtel - National Partnership for Women & Families – VP
Right.

David Blumenthal – Department of HHS – National Coordinator for Health IT
So what I wanted to do was to try to find the areas of agreement and then also identify the areas that need more work. Yes, David?

David Lansky – Pacific Business Group on Health – President & CEO
I like the idea of a phased or next steps, and I wondered maybe if John and the workgroup could break up this problem into two or three or four parts that could be tractable separately. It may be easier to get agreement on the urgency and stage them, given the urgency of what's happening in the rollout of exchanges at the state level. What pieces of this are most critical to get done in the next few months to support the launch of the state level cooperative agreements? For my sake, I'd say that the conditions of trust and interoperability is a very nice concept that deserves formulation at a national level for the reasons you just said in your last comment, John. There may be some piece of that top level of governance we could consider early. Then the next couple stages have to go through some development work. If we could lay out a timeline of what the criticality is and then as long as they're not too interdependent, have chunks of it come forward to us in stages over the next few months. That would be helpful.

David Blumenthal – Department of HHS – National Coordinator for Health IT
I think that the offline work that we need to do is to break this into chunks and flush out the chunks and bring them back with, let's say, a priority assigned to things that are broadly directional and things that are time sensitive. I think that's just acknowledging the fact that this is too complicated, I think, for the group

to feel comfortable voting on at this particular session, that there is an educational process that's going on. Do people feel comfortable with that? Okay. Yes, Judy?

Judy Faulkner – Epic Systems – Founder
I'm just wondering if we want to make it more complicated by adding one more component to it, and that is, what happens when information is sent to non-business associate systems, and it goes from there to others? In other words, we're catching all of the business associates and none of the other healthcare organizations. But another thing in interoperability is going to non-business associate systems as well. I don't know if that gets caught here, but that could be a bigger area of privacy leakage.

David Blumenthal – Department of HHS – National Coordinator for Health IT
I think that issue would have to be handled under the broad rubric of conditions of trust and interoperability. That's a case of that general situation.

Judy Faulkner – Epic Systems – Founder
Yes. Thank you.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Thanks again, John. We'll adjourn for lunch.

(Lunch break)

Judy Sparrow – Office of the National Coordinator – Executive Director
I'll turn it over to Dr. Tang to open up the afternoon session.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Good afternoon, and welcome back from lunch. I know it was a quick one. We have two more workgroup report outs this afternoon and we have a hard stop at 2:45, so we'll get underway right away. Micky Tripathi is on the phone, and David Lansky is here. I believe Micky is going to kick off the discussion, correct?

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO
Good afternoon. Today we're going to talk about the latest set of recommendations from the information exchange workgroup concerning provider directories. What we wanted to do was report out on the most recent deliberations we've had related to one set of provider directories and then tee up what we're going to be discussing over the next month related to another set of provider directory recommendations. Let me ask if you could advance the slide, please, David. I apologize for not being able to be there in person.

This is the information exchange workgroup membership. I just wanted to be able to give credit to everyone for all the hard work in what has been sort of a complex discussion of a complex issue. If you could move to the next slide, please, David, this is the group of people who deserve extra special credit, the provider directory taskforce who have been intensively engaged in conversations related to the recommendations that I'm about to describe. I want to give particular credit to Jonah Frohlich and Walter Suarez, who are the cochairs of the taskforce and who have done tremendous work in helping move us through this conversation and getting us to this initial set of recommendations.

What we want to accomplish today is, first off, just to sort of tee up that the information exchange workgroup is deliberating recommendations on provider directories of two flavors essentially, and I think I described this at the last policy committee meeting. We're looking at entity level provider directories and what we call individual level provider directories where really the distinguishing characteristic is how much detail is contained in the directory that you're talking about. So an entity level directory would be one that has information about organizations or entities, but not necessarily information about the individuals who are employed by or who are living within an organization or entity, whereas an individual level provider directory would provide information down at the level of individuals who would get their access or connectivity to health information exchange activities through the entities that are in the entity level directory.

We decided early on to stage our recommendations and to focus first on entity level provider directories to support meaningful use stage one transactions, which is what we're going to talk about today, and for the next meeting, what we'll present recommendations on are policy options for promoting creation of entity level directories with a set of characteristics and then recommendations on individual level provider directories. But today what we want to talk about is recommended characteristics of entity level provider directories. Then, as I said, we'll talk at the next meeting about what might be some policy levers to promote the use of, the creation and use of such entity level directories that would have such characteristics.

What we did is laid out a framework for the taskforce that would sort of guide our thinking on this. We broke it down into two broad types of activities: one related to, on the left side is sort of the requirements and options of provider directories, which, sort of taken together, are what I would say sort of define the characteristics of entity level provider directories. On the right-hand side what you have is once you've gotten your arms around that, then we want to have deliberations about what are the available policy options for helping to instantiate in the market the types of provider directories that we believe will help facilitate more rapid and broader health information exchange in the future. Today, as I said, we want to talk more about the deliberations that we've had on the left side and then, at the next policy committee meeting, talk more about deliberations about conversations on the right side.

We've got a set of recommendations that actually are really related to or are in the categories that were just described in that framework that I just showed. First we're going to talk about users. In each of these, we'll just talk about some general guidelines or principles that guided us and then some specific recommendations. The principles related to the users, meaning who would be the ones who would use the entity level provider directories are, first and foremost, wanted to be able to include anyone involved in the exchange of patient health information. That would include submitters, receivers, requestors, or providers of patient health information. We would expect the entities who are a part of the directories to abide by Nationwide Health Information Network governance guidelines and standards.

We certainly want to coordinate the user details with the privacy and security tiger team, as they're also thinking about the same types of issues, but from a different angle, related to security, but they're getting into the question of entities, individuals, and the connections there. Deven and Paul are on the taskforce, as well as on the information exchange workgroup, and I'm on the tiger team, so we do have some hard connections back and forth. We want to make sure that we're aligned with respect to our recommendations.

Then finally, we want to include healthcare provider entities that may not have an EHR system right now, and really with an eye towards the fact that there still may be information there that's valuable for the purposes of exchange. That does add another dimension to what a provider, an entity level provider directory might look like, but there seems to be a fair consensus among the taskforce and the workgroup members that given the state of technology adoption today that having a provider directory that does not include such entities would be a series gap for a long time in the information that might be available.

That set of principles led us to the following set of recommendations related to the users, which would be to say that the following entities ought to be listed in an entity level provider directory. So the definition of entities in this case would be healthcare provider organizations, so that's really the HIPAA definition of providers, so entities that are providing healthcare services: hospitals, clinics, pharmacies, labs, nursing homes; other healthcare organizations such as health plans, public health, health information exchange organizations; and then, finally, other organizations involved in the exchange of health information, such as business associates and clearinghouses.

Next slide, please. Who would not be included in the entity level provider directory? Firstly, individuals, by definition, as I said, we're focused on the entity level right now, so there would be no requirement to have individuals in the entity level provider directory, and these do not envision, either at the entity level provider directory or individual level provider directory do not envision having patients listed in the

directories. These are focused on providers, as the name suggests. Certainly entities that are not involved in the exchange of patient health information would not be included in the provider directory.

There are a related set of policies and guidelines that we'll take up in the business model, but that begs questions of how would entities become registered in such a provider directory, and how would we validate that the entities are who they say they are? We take that up in the business model conversation, which is a couple of slides in.

Next, we talked about the users. Now we want to talk about uses and functionality. The guidelines that we adopted in thinking about this were, one, that the message and assumption that the message sender knows where the message needs to go, but may not know the complete address, so that the idea is that often you're in cases where the organization is known, but sort of the computer address isn't known. So the organization is familiar, but the exact Internet address isn't known, and you need that obviously to send the information electronically. That messages can be sent over the Internet using standard Internet protocols, that message security is carried over agreed upon mechanisms like PKI, and we're making no assumptions regarding any specific HIE services or functionality that needs to be in place, so this is the idea is that this ought to be technology neutral and apply to health information exchange as a verb and not specifically instantiated in any particular case.

That leads to a set of recommendations related to uses and functionality, which are about saying that the provider directories ought to support directed exchange, which is both send/receive, as well as query/retrieve, which is sort of a double push kind of model. But the idea again is that this is not trying to be focused on any particular type of exchange, but that they ought to be able to support both the near term directed exchanges, as well as more elaborate types of exchanges going forward. That they ought to provide basic discoverability of the entity, that they ought to provide basic discoverability of information exchange capabilities, so I ought to be able to look up the Internet address of the entity. I also ought to be able to look up what their capabilities are in terms of what types of messages they can receive. I ought to finally be able to look up their security credentials so that I know that this will be a secure transaction.

In appendix 2, we've outlined sort of a more detailed discussion of specific use cases that we walk through with the workgroup. In each of these use cases, gave some focus to where an entity level provider directory would provide value in each of those use cases. I won't go through that here, but certainly I'm happy to answer any questions about those use cases if any members of the committee have them. They're provided to you in the appendix.

So next, we move to, we've talked about users. We've talked about uses and functionality. Now we want to talk about content, what actually would be in the provider, the entity level provider directory about each of the entities. Some of the general guidelines are that the focus of the content needed to be really about having functionality that's both executable and valuable. You don't want to be putting information in there that can't be used, or is unusable in certain ways. Also, you don't want to be putting any information in there that's extraneous that's won't be used for anything because it's not valuable. That the basic content requirements should limit the need for frequent updates, meaning that the directory itself, sort of a database principle, is that you want the directory itself to be as static as possible so that you're not always having to change it.

For content that requires frequent updates, the idea would be that the directory provides pointers to entities where up-to-date information can be found so that you're not having to update the directory itself, but that you're essentially decentralizing or federating the updating of it, and the directory itself just contains pointers to the places where those updates are maintained. Finally, for content that requires updates, trying to push the responsibility to the end user to the greatest extent possible is another sort of core principle that we don't want to be creating an infrastructure for the updating of data. We want the data to be updated as a part of business processes.

That leads to a set of recommendations on content that the entity level provider directory content should be limited to the following categories of information. First and foremost, a set of information related to

demographics and identification information of the entity, so certainly name, addresses of the sort of formal name or legal name and addresses where, in this case, we're talking about street addresses of the entity, other familiar names that the entity might be known as, and this would be sort of an entity responsibility to say here is the formal name of our practice, but we're also known as MGH. We're also known familiarly as these other things, so being able to put that in. Then also some information on human level contact, meaning if I need to talk to a person, is there information that I can get there for how to contact a person to actually talk to.

Then in terms of information related to information exchange services, the content related to relevant domains, as defined by each entity, so what does that mean? You can imagine that there are entities that have multiple domains under a single legal entity, but what they would like is, either from an IT perspective or the way they've organized their business, they actually keep that as multiple, separate, addressable domains from a network perspective. What might be an example of that? You might imagine that Kaiser, for example, Kaiser North, Kaiser South, Kaiser East, Kaiser West, that they would rather have that be the entities that are listed from a network addressing perspective, have it listed regionally in that kind of domain structure rather than having Kaiser as a single domain that things were addressed to. Whereas another organization like Partners may choose to say, we just have a single domain, and we would like everything to be directed to a single domain. Again, every entity would define that on their own, and the idea is that the entity level provider directory needs to be flexible to the variation that we see in the market because there is tremendous variation in the market on almost every dimension here.

We also would like the content to include protocols and standards supported for information exchange. Some of those might be what type of addressing is necessary, what type of interchange happens. Is it SMTP, REST, CCD, etc.? In this case, as I described before, certainly the recommendation would be that you'd be able to have some kind of pointer structure so that the directory integrity is static, but that it is able to point to other sources of information that may be more frequently updated. But at the end of the day, it may be that the entity level information has to be in the directory itself, and that is just something that is more of sort of a practical consideration, as we go forward, about how sort of robust and dense the federation is that you're able to accomplish here.

Another sort of item that we discussed at the workgroup is having sort of a general inbox location, if applicable, for message pick up or drop off. What do we mean by that? What's meant by that is that you can imagine that an entity level directory, in some ways, and I'll speak sort of loosely here, is kind of like saying I want to look up just the right-hand side of an e-mail address without knowing the left-hand side, where of course you can't really deliver an e-mail without knowing that it is paultang@stanford.edu. It's like saying I'm just going to look up the right-hand side of the e-mail address without regard to the left-hand side.

The idea was that because it's an entity level directory, we might want to have some convention that says that if you're in the directory, and if an organization wants to just send something to you, that there is a place, a default place that things can be sent electronically, and that would be sort of the idea of a general inbox location. Not necessarily a requirement, but something that enough members of the taskforce and working group thought could have some additional value and increase the likelihood that such a directory would be used. Then, finally, security, basic information about security credentials: type, location for authentication, etc. There's obviously a connection here between this and what you're going to be hearing from Paul and Deven from the tiger team on entity level authentication.

Moving next, we talked about users, talked about functionality, talked about the content of what should we have with respect to each of the entities, what kind of information on each entity, and then we started to focus on business models. How should we think at a higher level about how these entity level provider directories might be sort of constructed, and now might they live in the market, and how do we think about that? What should be the architecture of them, and do we have a perspective on that or not?

Some of the general guidelines there are that there's a strong sense that the business model ought to support national scalability, as well as harmonization and interoperability across localities and regions and

states, so that the entity level ought to have some level of national coordination and orchestration. That certainly the business model needs to provide flexibility to accommodate for various HIE architecture and infrastructure approaches, as I described before. That we want the maintenance responsibility to be pushed to the end user participant, and to that effect, there would be guidelines for registering information that would need to be established, so what is the set of standards, what's the set of conventions that would allow an end user participant to update their information? That would be a certain set of things that would need to be established. Then, finally, as I described, we wanted that the security part of this from a business model perspective is something that we need to coordinate going forward with the privacy and security tiger team recommendations and other considerations as well, and governance is another big piece of this is a coordination point with the governance workgroup going forward.

So the recommendation related to the business model and operating approach is, as you probably derived from the general principles, an Internet like model that has national level of coordination or orchestration, but a federated approach in terms of how its sort of instantiated in the market. The components of that would be certified or perhaps accredited is maybe a better word, but some type of validation of registrars that are accredited or go through some kind of registration process so that there's a standardization and a level of service related to being able to receive, process, accept entities into and to remove them from the ELPDs, that there ought to be national guidelines that guide that.

That there ought to be reciprocity and publication to this national registry system, so the idea would be that entities registered by one registrar are able to be recognized across the entire system, that the individual user, that Sibley Hospital would not have to say, well, there are 15 registrars across the country, I need to register with every single one of those in order to insure that my data is nationally available. That you would register with one, and it's visible to all, and that each registrar publishes directory information into a national provider directory registry system that, like DNS, will support identification across registrar domains. That the ELDPs are maintained by the registrars, but cross-referenced through the system, again very similar to the way the DNS architecture works today.

There are certainly some possible roles for federal government, and we will get more into this in the next round of recommendations, as we think about policy options, but some examples of those might be national standardization and harmonization that having some agencies themselves be registrars, for example, Medicare, VA. Then, finally, to the greatest extent possible, building on existing national and federal sort of foundation directories that already exist, and those might be the most obvious places to go, as you think about sort of a core foundation that you could build on and directories that are already maintained as a part of normal day-to-day business processes, so thinking about PECOS, NPES, and NLR, for example, just to name a couple.

We think that the benefits of this approach that there's national scalability, the ability to have and have that help foster interoperability across regions and health information exchanges, and that it's relatively simpler to implement if it's at the entity level and done nationally and done in this Internet like model. There are certainly issues with respect to data management and conformance across industry. That's a little bit of what we will be taking up, as we think about the policy options and the policy levers to help facilitate this going forward.

Let me pause here first because I know I've covered a lot, and this is by way of the recommendations on characteristics of provider directories. What I was going to describe next is really just some high level considerations just to give you a sense of what are the topics that we're going to be discovering, as we think about policy options that might help promote the use of enterprise level provider directories, as we've just described. But this is sort of the end of the detailed discussion about the recommendations themselves. … invite David or any other members of he workgroup or the taskforce who are on the policy committee to weigh in as well.

David Lansky – Pacific Business Group on Health – President & CEO

I don't have anything to add. It's great work by this workgroup and the taskforce. I will say we had a similar discussion in California last week, and the work that this group has done is really very harmonious with the discussions we're having at the state level and very helpful to those discussions, so thanks for all

your work on this. I guess we should have a round of discussion here. Do you want to say any more about the policy table that comes next, Micky, or do you want to stop here for discussion?

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO
Yes. I can go either way. If it makes sense to stop here and answer questions, I'm happy to do that, or it's just one slide on the policy options, so ….

David Lansky – Pacific Business Group on Health – President & CEO
Why don't you just review that and then we could have the full discussion?

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO
Actually, there are two slides. Sorry. The policy questions that we're going to be taking up in the next round of deliberations of the taskforce and the workgroup are which business models does it make sense for the government to try to promote with respect to sort of policy levers. Not that we're trying to pick a particular business or a particular business model, but if we're going to have entity level provider directories in the market as rapidly as possible to help facilitate rapid adoption of health information exchange, we've got to have some kind of perspective on what it is that we want those policy levers to be pulling toward.

What are those potential government roles and levers? What's the appropriate level of depth in terms of policy recommendations? There's certainly in a part of the recommendations are almost certainly going to be about recommending that the standards committee develop standards in a certain set of areas. We certainly, from a policy perspective, don't want to be overly prescriptive and sort of step on the toes of the standards committee or lock the standards committee into a particular set of architectures or ways of doing things, but want to be able to provide sort of policy guardrails. So just thinking about what level of depth we need to go into in terms of recommendations is one of the things that we're going to be considering.

Then, finally, what's critical and necessary to meet our goals? Certainly in the back of our minds, and often at the front of our minds is the minimal necessary principle. We want to be able to do the minimum needed to get this established and off and running so that we're not circumscribing either marketer or government actions too much.

What we've done here is try to provide an overall mapping of what some of those levers might be and then just put them into different categories just to make it a little bit easier to think about. On the left, you have, as I've described, the business model recommendations that we've come up with, this Internet like model, operating similarly to DNS, and we've divided up the potential policy levers and government roles into four broad categories. One is a set of potential levers related to the infrastructure of the ELPDs. Another is how we would—levers that would facilitate maintaining data quality and accuracy. Another is about the standards and interoperability requirements, and then, finally, governance and participation.

You can imagine. I won't read through every one of these, but going down some of these, there's sort of a whole spectrum of potential levers that we'll be considering, some of them related to standards for getting information into and out of the ELPDs, as well as for being able to consumer the information as a user, and perhaps leading to certain requirements related to EHR certification and having EHRs certified to be able to consume information and perhaps even be able to populate information in an ELPD. There is certainly a whole set of recommendations that might be related to the NHIN from a governance perspective, from a standards perspective as well, and as well as finally a set of standards that might be, as I described from the standards committee, related to data elements, interoperability with EHRs, open interfaces and the like.

I didn't want to go into too much detail here, but just wanted to give the committee a flavor of what we're going to be taking up next, as we dive down, as we sort of complete our deliberations on entity level provider directories and then move to the individual level. Finally, the next steps are wanting to focus, as I said, on the policy options. We will then be diving into the individual level provider directories in sort of the same framework where the idea is that the entity level, individual level directories, without getting too

far ahead of where the workgroup conversation has gone to date, but the individual level. There's sort of recognition that because of the level of detail there and because some of it is state or regional or at least sub-national specific, that there may be a need to allow a little bit more flexibility in terms of the conformance of how individual level provider directories get constructed and are maintained. But we would certainly want to maintain some type of direct link or mapping to the entity level provider directories. Indeed, it may be that the entity level provider directories, because they provide sort of hooks to hang things on, to speak loosely, might be a way of actually fostering the creation of individual level provider directories at the sub-national level. As I said, we'll be coming back to the policy committee at the next meeting in December with recommendations on these two areas.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Thank you, Micky.

David Lansky – Pacific Business Group on Health – President & CEO
I think we can have some discussion and questions.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
I think your recommendations revolve around who is in it, what's in it, and some operating approaches, correct?

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO
Yes.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
And those are what you would like us to respond to, to go forward.

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO
Yes, please.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
At the entity level provider directories. Comments, questions, Charles?

Charles Kennedy – WellPoint – VP for Health IT
My question, Micky, is at the entity level, like when you say we are addressing a piece of correspondence to the right of the e-mail address, would you see any function insuring that it goes somewhere within the entity? In other words, is there a governance function that might take a look, or in some way assess whether there's the next step of getting it to the individual provider, or would that be totally up to the entity?

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO
The assumption has been that that would be totally up to the entity. That what we're saying is that the provider directory provides the routing information to get it to the front door, as it were, and then it is up to the entity to pick it up at the front door and decide what to do with it from there.

Charles Kennedy – WellPoint – VP for Health IT
Did the workgroup have any experiences or pilots or anything that it could point to about the effectiveness of that approach?

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO
In general, you obviously want to have some further information that is contained, and the use case has kind of specified this that it's either in the header or the message itself that will specify an individual provider and/or a patient. So somewhere in the message itself, whether it's in the header or the message itself, there would need to be the information that would allow the electronic health record system to then do the onward routing, so we're not saying that that information isn't necessary for it to be meaningful or useable. We're just saying that that isn't information that would be at an entity level provider directory.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Paul Egerman?

Paul Egerman – Software Entrepreneur
Thank you, Micky. A great presentation, and I just want to thank you, Micky, for your leadership. This is actually a surprisingly difficult topic, and so you've done a great job in helping the workgroup and the tiger team get through it all.

I have an observation, but actually I first was going to comment on the question that Charles raised about making sure that a message gets to the intended recipient. There is a vehicle to do that. One could always simply specify a standard for fundamentally a receipt since that is what is really important to do, but the current state of the art actually is to think about how e-mail works or even how interoperability works is you get it to the front door of the organization, and the organization is responsible for delivering it the rest of the way.

The comment I had about the presentation is, I wanted to actually relate this presentation to the presentation that we had earlier from John Lumpkin on governance where he talked about validation and validating whether or not somebody can be a member of NHIN or NW-HIN, and here we have this concept of registrars who register people into the entity level provider directory. One possible way to bring these things together would be that the registrars could also be participating in the validation process, so that registrars are the ones who validate whether or not the entity should participate. If they agree that they do, they basically are registered, and a directory could be possibly a directory of all the participants in NHIN, or it could be a superset could include some organizations that are not necessarily a part of this NHIN, but could indicate which are the participants in NHIN. My observation is that this actually does coincide with the governance presentation.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Deven?

Deven McGraw - Center for Democracy & Technology – Director
I would agree with Paul, although we have sort of a number of things proceeding here that are reliant in some ways upon us sort of pinning down some of this governance stuff. So while there's going to be shades of some things in our presentation and, as Paul just pointed out in this one, I think it will probably be incumbent on us as a policy committee, since we left some questions on the table with governance, to try to wrap all this stuff up, as we get some more clarity on that. Yes, you could see a registrar's potential validation entity, but we still don't know what we're doing with respect to validation entities, so I think we have to keep that in mind.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Art?

Art Davidson - Public Health Informatics at Denver Public Health – Director
I also want to thank you and Walter and Jonah for the fine work that's happened in this workgroup. It's been excellent. I have two areas I'd like to ask about. I understand that right now we're talking about this entity level provider directory and, at a future date, we'll talk about an individual provider directory. But what about the situation where it's role-based, and you don't really know to whom it's going? It's to a role. For instance, when something is going to a state health department, it could go to the epidemiologist at the state health department, to the laboratory at the state health department, but you don't know who the state epidemiologist is. You don't know who the laboratorian is. When will that be addressed? That's one question.

Then the second one is, in the presentation and in our discussions, I agree, most of the work so far has been based on the Internet model as a business model. I just wondered. Are there any other sorts of models that exist out there in other industries? This morning I was thinking as well about the telecom

industry or the banking industry. How are they different or the same as this Internet model that we're now thinking about using? Is there something we can learn from a different industry?

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO
Just dealing with the second one first because it's easier for me since I can just say I don't know enough about those industries to really speak to it, except one thing I will point out though is that healthcare delivery is much more fragmented than almost every other industry in the U.S. economy at least or ever other economic sector, so that's certainly just one of the fundamental landscape kinds of considerations with healthcare delivery that makes it very, very different than most other industries that they've been able to achieve a lot of scale. You mentioned telecom and banking. In part, by very large organizations being able to scale across the country and resolve some of these issues, and then have entity level kinds of interoperability that ends up sort of capturing a very large fraction of the transactions that need to happen in the industry, whereas in healthcare, particularly on the ambulatory side, it's unbelievably fragmented.

We've done some work looking at commerce department data on concentration and physician offices are the second most fragmented recognized economic sector in the country. The only one that's more fragmented in florists, and that's just one of the features of healthcare delivery that makes it more difficult. But certainly would welcome other people's expertise in those other areas who could speak to that better.

In terms of your first question, Art, I think that part of that is going to be things that could develop by convention or perhaps by policy, as we go forward, to say that the entity level directories ought to contain a little bit more information, perhaps addressing information that might, as I said, either by convention or by policy, start to say that not only do I want to have a general inbox, let's say, but we want all hospitals to have emergencydepartment@sibley.org, and cardiology@sibley.org, and that everyone would sort of, either again by convention or by policy say, there'll be some standard nomenclature about the inboxes within a particular domain so that people wouldn't have to know those on their own.

In terms of it getting to the right person within an organization, again, I would just go back to the question, I think, that Charles had that the assumption is that the entity representations that is constructed, remember, by the entity delivers it to the right place with the assumption that they're able to consume the information, whether it's in HL-7, CCD, what have you, in a way, but by their system that will then direct it to the right place. Because the entities themselves are constructing that, the assumption is that they will be able to consume the information and get it to where it needs to go.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Anything more? I hope by electronifying records, we'll not only have less fragmented care, we'll have more forests. Thank you very much, Micky. Appreciate it, Micky and David.

David Lansky – Pacific Business Group on Health – President & CEO
Do you want to take a vote on recommendations?

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Yes. Would someone like to make a motion?

David Lansky – Pacific Business Group on Health – President & CEO
I can do so. I move acceptance of the recommendations that were proposed today.

David Bates - Brigham and Women's Hospital - Chief, Div. Internal Medicine
Second.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
And all in favor?

M
Aye.

W
Aye.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Opposed? Abstained? Great. You have it.

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO
Great. Thank you. Let me just finally, I just want to also just again give a lot of credit to the entire workgroup and the taskforce, but also to Jonah Frohlich and Walter Suarez and Claudia Williams from ONC who were incredibly helpful in their leadership in helping us through this.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Good. Yes. Thank you.

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO
Thank you.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
We managed to steal back a little bit of time for privacy and security. We decided we would never allocate only a half an hour to them. Then I saw 40 minutes. That's a little better, but now we're back to about 55 minutes. Deven and Paul Egerman are going to lead that discussion.

Deven McGraw - Center for Democracy & Technology – Director
Thank you very much. Our topic is a little bit technical too, so we're kind of hoping that we'll just sail right through, but we never get that lucky. I want to acknowledge the tiger team members, as always. Notwithstanding that our schedule is a little more forgiving than it was over the summer, it's still an enormous time commitment for the people who are on our workgroup, and we very much appreciate it. We wouldn't be able to sort of continue to come to you with particular topics to continue the work that we are doing to flush out a comprehensive privacy and security framework to govern health IT and health information exchange if we didn't have people continually getting on the phone with us, wrestling with these topics. Very much appreciate it and, of course, we always thank the members of the public who join our calls, who push us back, who push back on us and ask us hard questions, and continue to make this job a challenge. It wouldn't be worth doing if we couldn't have that robust dialog, so we thank everybody.

So we want to first do a little level setting about what we're talking about today and what we're not talking about today. We know that in stage one of meaningful use, there are some minimal requirements to exchange identifiable clinical information among providers for treatment purposes with some exchange for public health as well. But we expect that the exchange requirements are going to increase in stages two and three. We don't know in what way, but I think we're pretty confident that in order to sort of go up that curve that we have seen multiple times with respect to the stages of meaningful use, there's going to need to be more robust exchange among providers in these later stages.

What we did in this latest set of discussions is focusing on a trust framework for information exchange between EHR systems. Specifically, we need to make sure that when one EHR sends information to another EHR at an entity or organization level, we need to be able to validate that the organization is who it says it is. Digital credentials are a common mechanism for doing this. Specifically, does the organization actually really exist? Is it the entity that I intend to send it to, and how can we be sure that, for example, if I send it to the entity that I expect is, for example, the Palo Alto Medical Foundation, that it really is getting to the Palo Alto Medical Foundation and not an entity that is spoofing itself as the Palo Alto Medical Foundation because it wants to gain the patient data and run off with it?

To be specific, we're looking at these trust rules at an organization or entity level. The scope of our recommendation does not include authentication of individual users of the EHR system. Another way to think about this is the handshake between the two EHR systems is the two machines, not the individual

users that are within those organizations and how they get identified and authenticated as being able to use those systems. We're not touching on that.

With respect to individual users, provider entities and organizations must develop and implement policies to identify proof and authenticate their individual users, which is already a requirement of the HIPAA security rule. So with respect to the entities that are participating in state one of meaningful use, they have already – they already need to do this with respect to the individual users within their system. And so because we like to, in our slide presentations, give you a little bit of breakup from all the words, this is just a demonstration of what we mean when we say we're talking about authentication at the entity level, and so we're really, again, making sure that those machine-to-machine handoffs of information are accurate. If I'm sending it to – if my intension is to send it to another provider organization that I can be sure that when I press the button on the machine, it's going to the right place. Then I want to turn it over to Paul to make sure that – to see if he has anything to add to what I've already said and then to continue along with our recommendations.

Paul Egerman – Software Entrepreneur

Thanks, Deven. I think you've done a good job of laying the groundwork to continue on. The first thing I want to do is simply review a couple pieces of terminology. First, we're talking about this thing called digital certificate, which is underlined on the screen. I'll do my best to explain what a digital certificate is.

If you thought about, for example, like a drivers license or a passport that you might share at an airport, the purpose of those documents are to sort of authenticate, to check to see who you are, and so they're used to check to see who you are. Digital certificates in the context of which we're using it is used to check to make sure that the entity or the computer system is who it claims to be. That's what a digital certificate is used for and does contain some amount of information about the entity in the certificate.

There's another word that is underlined here, which is credentialing. We talk about credentials in a healthcare concept. The physicians automatically think about their medical credentials. That's not what we're talking about here. In this context, the term credentialing actually deals with the process. It's really simply the process of obtaining or applying for a digital certificate. So when you go through our slides, we try to make this clear by saying that when we talk about credentialing organizations, and then we put like, slash, issuing certificates. That's the basic terminology.

We also have some comments that we want to make sure that were sort of like baseline assumptions that we had. The first one is very simple, exactly as Deven says, we want a high level of assurance that the organization is who it says it is. There's no spoofing. But as a sub-bullet, we also, as a team, wanted to balance, achieve an appropriate balance between security and costs. In other words, we weren't willing to do this at any cost at all because the system has to work.

The second bullet is very important to make sure we be clear that entity authentication, these certificates are important, but it's not like it's the sole measure of security. In other words, we were saying it's like a necessary security measure, but it's not a sufficient security measure. It's a necessary piece, but it's not like by itself this does everything. And the third assumption is the governance group, which we heard from this morning. We assume that that group is going to develop an infrastructure for adherence to a framework of policy and security practices, so we're saying this is important, but we're not trying to hang everything on the digital certificates. Those are our overall comments.

Now based on that, we have a series of six recommendations. Six may seem a lot, but we sort of chopped up the whole issue into six questions. We posted it on the FACA blog. We got excellent response from the public. We got over 60 terrific comments, and these comments were a page or two long. People e-mailed, faxed them to us some very important, spirited discussions, which we took into consideration, which influenced our discussion.

We changed our six questions into recommendations. The first recommendation is really sort of like which provider entity should be issued digital certificates? And our answer is, in some sense it's simple because all entities involved in health data exchange should be required to have digital certificates. Let

me give you some examples. The reason we gave the examples is we wanted to clarify that we really do mean all entities, not just covered entities. It includes business associates, PHR, providers, retail pharmacies, DME suppliers. We listed some examples of that.

The second recommendation is what are the requirements for an entity to be issued a digital certificate? We came up with two requirements. And so the first one you see of the two requirements is that they have to be a legitimate business. They have to be a valid business entity. The second requirement is they have to participate in the type of healthcare transactions required for meaningful use. Those are the only two requirements.

The two other comments that we made are the credentialing organizations. Those are the organizations that will issue the certificates. Should rely on existing criteria and processes when possible, and the reason we say that is, well, deciding whether or not a healthcare organization is a legitimate business, there are already processes in place to do that. So there's a process to define an NPI and commercial insurance companies have capabilities to make sure that before they sign insurance numbers to entities and pay them that they really exist. And so we assume that we want the credentialing organizations to leverage one of those capabilities.

The other thing is, comment that you see, the third bullet is we did not impose any additional privacy and security requirements to receive a certificate because we assumed that that's what the governance workgroup will be doing. Although you see in italics, we said we did not impose anything else at this point in time. So we're sort of saying, at some point in time, we could add additional requirements if we want to, but we felt that governance should be doing it, saying this is the minimum set of requirements to get a digital certificate.

Deven McGraw - Center for Democracy & Technology – Director
Being consistent with what Paul said earlier, we weren't trying to use the digital certificate and load it up as a policy lever for enforcing a lot of other policies and practices that we want to see because, quite frankly, we think there ought to be other mechanisms to do that. If that turns out not to really pan out, we might readdress that question. But at this point, I think, even though we don't have the governance workgroup recommendations completely pinned down, I think, at a minimum, government plays a role in enforcing privacy and security requirements. And to the extent that we get there, I think we would like not to be able to use the digital certificate process as a lever to enforce a lot of other things. I skipped this whole slide … ready to be done.

We think that, given the number of entities that are going to need digital credentials and need digital certificates, you're going to need multiple credentialing entities to support the issuance of certificates across that larger number of entities. And so we provide an example. Vendors could play a role here. State agencies could be authorized to issue them. We also should leverage existing processes such as the federal bridge, which issues digital certificates for entities that need to share information with the federal government. And we also wanted to note that entities like health information organizations that are regionally or state based, and who otherwise have really a knowledge of the existence of the providers and entities in their area, could be quite ideal for issuing digital certificates to their providers.

Now digital certificates should be renewed at least every year or any time there is a material change in the evidence that was originally submitted to justify the certificates. Now we mention here also an expiration date, so this is a way to operationalize an annual renewal that if the certificate has an expiration date in it, then you'll know you have to get it renewed on an annual basis. Tricky?

If we're going to have multiple entities out there doing the credentialing, how can we be sure, since ultimately what we want is a high level of assurance that the organization is who it says it is, and can get a digital certificate? If we're going to allow multiple parties to play here, how do we get that high level of assurance? We have to be able to trust that the people who issue the credentials are doing so appropriately, and so we want an entity who is willing to assume the risks, but that means they have to be held accountable for a high level of accuracy or assurance in meeting any standards that we might set. So we actually recommend that ONC establish an accreditation program for reviewing and authorizing

certificate issuers. And we also note that while we've called for an annual renewal here, we also want there to be some level of transparency for credential issuers so that it's not just – they've got some transparency about their operations, so we can monitor.

They can be monitored, and then problems can be quickly identified. Again, we sort of are looking very much at a federated model here where there can be multiple players, but ultimately there needs to be some accountability if we want that high level of assurance. We've called for accreditation. Of course, we also note that there is ongoing work in governance, and we talked about it this morning, that would need to evaluate this requirement and in the context of what we're doing on governance because ultimately what we're asking for is governance of credentialing.

Paul Egerman – Software Entrepreneur

The next recommendation relates to standardization and certification. We're talking about EHR certification related to digital certificates. This is a very interesting issue. When Deven and I did the agenda for the tiger team, we laid out an hour for this discussion because it's like the heart of our whole recommendation. Much to our surprise, every member of the tiger team was like completely supportive of standardizing and doing certification around this. It's like we had almost violent agreement. We were so unaccustomed to having agreement from the tiger team members, we didn't know what to do. It was like astonishing, although lest you think that the tiger team has become like kittens or something, we did have a disagreement about how to wordsmith. That's why it says should select or specify. There's some discussion whether or not the standards committee selects or specifies, so we put in both.

Basically, this is a very strong recommendation. We think it's very important that the standards committee establish the standards for these certificates, that there be certification criteria written against, which means in stage two what we're saying is that the recertification criteria and testing to make sure that when these transactions are sent from one entity to another that they check to make sure there's a certificate and do the correct thing. I want to do my best to take a minute and explain why this is very important.

If I would recall one of the meetings that we had many months ago where Neil Calman talked a little bit about his experience in his own medical group in trying to hook up with a laboratory, commercial laboratory system, and what he described is a very common thing, which is, it took months and months. It was expensive and frustrating, and then it had to be repeated again when he did the next laboratory system, and so you got the sense that this is a process that's going on right now. It's unfortunate. And what you'd like to do is you'd like to replace it with a process just like plug compatible instead of the frustrating process that Neil and medical groups go through right now. You'd like to have a process where they just type something on a screen, and you'll … wait, please wait. And then it says one more minute, and then it's done. That's what you'd really like it to be.

That's not where we are, and I don't want to tell you that digital certificates will make that happen because that's not the case either, but it's one of the components that is necessary to get to that vision. This is one of the steps forward that will help us get to that vision. It's one thing that we don't need to repeat over and over again in terms of trying to figure out how this all works. So this is very important. This is the core of our recommendation that this would be part of hopefully stage two of meaningful use, that it will be tested. It'll add, and essentially this is actually a security recommendation as opposed to a privacy recommendation. People sometimes have trouble between what's privacy and security. This is really a security recommendation, but it will add to security, and it will reduce the cost of implementing these systems.

There was a sixth question, which is also to specify what are the types of transactions that will require certificates, and basically the answer to that was really any transaction that includes identifiable information about a patient, so that could be healthcare transactions. It might be sort of administrative transactions too like eligibility verification could also be involved. Then you see some cryptic message at the bottom about both transactions can be used to transfer multiple documents. Basically we did specify it. I don't think we quite wrote it exactly right on this slide. We did also specify that if you're sending a sequence of transactions, maybe you're sending 100 lab results or 1,000 lab results at once. You only

have to authenticate once with a session. You don't necessarily authenticate for each transaction. We wanted to clarify that.

These are our six recommendations. We wrote them as six, but it's really one recommendation to create a process around digital certificates to create certification, to create standards and certification criteria around it and to make it a required process of the certification process.

Deven McGraw - Center for Democracy & Technology – Director
Well, and I would add creating an accountability infrastructure for, again, making sure. It's not just about the certification of the systems, but also the piece of this that touches the most on governance is, while we acknowledge there'll need to be multiple credentialing organizations, we need a way of holding them accountable for doing it right.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Thank you. Judy?

Judy Faulkner – Epic Systems – Founder
That last bullet, not the dash, but the bullet, I'm having trouble reading that one. Am I just reading it wrong, or is it missing something?

Deven McGraw - Center for Democracy & Technology – Director
It might be missing a word. Examples of transactions that may require authentication of … yes, it has too many words in it. I'm a lousy editor, apparently. These are just – it actually should have….

Paul Egerman – Software Entrepreneur
For assurance doesn't belong there.

Deven McGraw - Center for Democracy & Technology – Director
Yes. It should say, "Examples of transactions that may require authentication of either the sender and/or the receiver include," so this was that violent wordsmithing that Paul was referring to earlier. It sometimes results in slides having some words that shouldn't be there.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Adam?

Adam Clark – FasterCures – Director, Scientific & Federal Affairs
Thank you. I realize most of everything is covered. You're talking about covered entities to covered entities. But as we get beyond stage one, start looking to stage two, stage three, as patients are interacting with the systems, are they going to require the validation that I am, who I am, or in many ways, if I'm a caregiver, that I can access the records or the information, the person that I'm providing the care for?

Paul Egerman – Software Entrepreneur
It's a great question, Adam. I turn back to our recommendation number one where we listed examples, and we did put in a group that we call PHR providers. The basic concept here though is still at an entity level. The reason we said is if there's an organization that is providing PHR systems to patients, and a patient wants their information electronically sent from their healthcare provider to their PHR entity, this is how you're going to assure that that transaction is going to the correct place. It's not doing assurance, however, about the individual patient, which is an interesting issue. It's actually the issue that the tiger team will be addressing next. So … feel like a building block. This is one foundation step, but it doesn't identify all the way to the individual level. We will be addressing that separately.

Adam Clark – FasterCures – Director, Scientific & Federal Affairs
That's great. Thank you.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

I have a quick question here, and it has something to do with this. You talked about … to require a digital certificate need to demonstrate, one, that they're a legitimate business, but, two, that they participate in a healthcare transaction required for meaningful use.

Paul Egerman – Software Entrepreneur
That's what it says. Yes.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
That's what it says.

Deven McGraw - Center for Democracy & Technology – Director
What we were intending to do here is we were talking about – well, no. It says they participate in the types of healthcare transactions required for meaningful use. This is our way of getting at really, quite frankly, anyone – the common way to authenticate on the Internet to exchange data is through digital certificates, but we were speaking to the need for healthcare entities to get digital certificates and, specifically, if we are not necessarily creating a separate process to credential healthcare organizations, but certainly we want to make sure we have an accountable process where the healthcare entity credentialing is concerned, and so we thought that, at a minimum, two things you should need to show is, one, you're a valid business and, two, you're actually in healthcare. And the types of transactions that we're concerned about are those that are involved in meaningful use, but we weren't trying to limit it to meaningful users. That's why it says you're participating in the types of healthcare transactions that are required for meaningful use.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Let me connect it to something that Judy asked about earlier, which is, and you have on your list, for example, PHR providers. So you can imagine, and this sort of goes to leave at the doorstep kind of comment, but you may deliver it to somebody who hangs a digital certificate at the doorstep, but what is the need for understanding where it goes after that? Just like we say, privacy protection should follow the data, should the authentication of the entity, in this case, follow the data as well. So do all the people who a covered entity send to another digitally certified entity, should the patient know where else it goes?

Let me try to expand upon that. The use, in a sense, said you want to follow the data for all meaningful use types of healthcare transactions. Are we not also worried about other transactions that happen after that, and was that data authentication?

Paul Egerman – Software Entrepreneur
Yes. It's a very interesting question. First of all, the reason we put in the meaningful use requirement, as a second requirement, is we wanted to be clear that we didn't just want it to be a legitimate business because we didn't want, for example, a certificate going to a florist. This has got to be a healthcare organization. Now the question that you're asking is, well, what happens if you send it to a legitimate healthcare organization? What about what they do with it subsequently? That's a good question, but it's sort of like a different question. It's an important privacy and security question, which is, how are they going to use it. That's not a question we're addressing with this set of recommendations. That is a question that I think our tiger team does have to address, and it's partially addressed so far, but does have to address.

Deven McGraw - Center for Democracy & Technology – Director
I think it gets to the issue of what is the weight that you want the digital certificate to bear.

Paul Egerman – Software Entrepreneur
That's right.

Deven McGraw - Center for Democracy & Technology – Director
We decided as an initial matter, based on the work that was going on in governance, that were not going to recommend using the digital certificate to bear the weight of all of the privacy and security questions that we need to resolve. Yes, there are questions, once it gets delivered to the right front door. What

does that entity then get to do with it, and who else can they share it with? All very legitimate questions, but I'm not sure that the certificate process should bear the weight of adjudicating them.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Let me separate that because I wasn't intending for the certificate to bear the privacy and policy weight. But whatever happens after that, shouldn't the disseminators of that information also need to know the authentication of the receivers? That's why I'm saying by limiting it to just the anticipated first use of the data be a meaningful use transaction, does that limit you in terms of who gets authenticated downstream? And you want to be….

Paul Egerman – Software Entrepreneur
It's a good question. In your question, are you suggesting a broader statement than just meaningful use?

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Well, or that everyone who transmits this information that was acquired in one way for one purpose also needs to demonstrate that they send it to authenticated entities.

Deven McGraw - Center for Democracy & Technology – Director
We already have a set of requirements among, I mean, again, we focused on exchange transactions among providers, which we know we have a set of them that we have to resolve for stage one of meaningful use, and we expect that there will be more. So we didn't necessarily leap wider and say we want to cover the whole exchange environment with this. Already, we have in the HIPAA security rule and privacy rule, quite frankly, requirements to be certain that when you receive data from another entity that whoever you send it to is the right, is the correct entity. In some respects, we're—

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
The trigger was your list of other entities, and one of those is PHR providers, and those people certainly do non-meaningful use, non….

Deven McGraw - Center for Democracy & Technology – Director
No, that's actually, so we actually listed them because one of the categories of exchange for stage one of meaningful use is to be able to share information with patients.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Right.

Deven McGraw - Center for Democracy & Technology – Director
The piece that we didn't get to is what requirements are we going to put on for individual credentialing to get copies of their users? But we certainly presumed that the need for issuing certificates to PHRs is because they've got – they're going to play a role in meaningful use. Plus you've got the HITECH provision that says if you're holding it electronically, the patient ought to be able to get it electronically and then have it sent to the entity or person of their choice.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Great. Art?

Art Davidson - Public Health Informatics at Denver Public Health – Director
It may be the same point here. I was just thinking, looking at the PHR providers that at some point a patient with a PHR may be asking for replenishment of some durable medical equipment that it's now going from a patient to a DME provider that isn't necessarily in the scope of what we've established as meaningful use here. I thought that the qualifier for meaningful use is somewhat limiting, and we want to get to the point where patients can be able to speak with their medical equipment providers without having to solve this issue, it must be for meaningful use.

Paul Egerman – Software Entrepreneur

Would it be helpful to your comment, Art, and Paul's comment, if we changed this from participate in types of healthcare transactions required for meaningful use to simply they participate in electronic health care transactions?

Art Davidson - Public Health Informatics at Denver Public Health – Director
That would be fine.

Paul Egerman – Software Entrepreneur
And one that satisfies.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Well, that's the same thing as saying wherever this health information goes to, you've got to know who that party is.

Paul Egerman – Software Entrepreneur
We already said that, but that's in a prior recommendation that each provider is responsible for authenticating that it's going to the right place, and so we've actually already made that as a recommendation. This is, again, a very specific security recommendation. It just tells them how you're supposed to do that, at least one of the pieces as to how you're supposed to do that.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Larry?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
Thank you for the editing. I think that addresses one of my questions.

Deven McGraw - Center for Democracy & Technology – Director
Sorry about that.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
That's good. That's the reason for doing this because it's great work, and the basic concept, I think, is really a powerful one that we should build on. My second question really addresses the sense of there are other ways to secure communication between entities. Existing exchanges have already implemented some kind of security, given that they're already under HIPAA requirements, and so is there any scoping of this that would help distinguish between the existing point-to-point communications that many healthcare providers have set up with other partners of various kinds? And the sense that we're moving into a much many-to-many world of, I don't have to have a dedicated connection. I can actually create on the fly, look someone up in a directory, know who they are, send them some information, and know it's getting to the place I intended to send it to. And the same that they know it's coming from someone, actually the healthcare provider, not someone who is spoofing me.

Paul Egerman – Software Entrepreneur
It's a great question, and it's also helpful that you mention look up the directory because we are coordinating with the presentation that you just heard from Micky Tripathi on an entity level provider directory, a mouthful, but the concept is that you could indeed look up somebody in the directory, because maybe it's not somebody you normally send information to, but you want to send to a specific commercial lab or pharmacy or a certain specialist organization. You can look them up and then go ahead and transmit the data. But I didn't quite understand your comment about the existing certificates. You're concerned that this will require people to redo what they have? Is that the question?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
Yes. For example, Kindred has connections with labs that we send information to, and they send it back, and it's really patient specific, and it has privacy requirements around it, and we've established secure connections with them, but I'm pretty sure it's not with this structure, so there may be digital certificates involved, but they're not set up with the notion of identifying the provider organization. We're securing a connection between two endpoints, and so we're using some leve of physical and/or virtual security to tie

down a connection. And having established a secure pipe, we're then sending data through the pipe, and there isn't the same sense of knowing the recipient. We're going through a pipe. Someone could hijack the endpoint. It's a different level of control than what you're proposing, but it's worked well, and we haven't had issues of security breaches around that.

Paul Egerman – Software Entrepreneur
It's a great question, Larry, but to me, it's equivalent to when we create standards for how you're going to transmit laboratory test results. That could be great, but that doesn't necessarily require you to change something you already have to implement that standard. What we're hopefully doing is establishing a baseline, so people go forward and implement new things will use this as the way they're doing it. And so I guess my response to you is, our recommendation does not require that you do over your existing connections, and sort of like the devil will be in the details in terms of, if our recommendations are approved, how it's written in the NPRM or in the IFR. But it should be done in such a way that you don't have to change what you already have, but that you have to establish a certificate, so going forward, you can be contacted through this methodology.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
Thank you.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Jim?

Jim Borland – SSA – Special Advisor for Health IT, Office of the Commissioner
Yes. I apologize for having to step out, and if you answered this question, just tell me to read the slides. Art brought up an interesting kind of use case, the idea of a patient mediated exchange where the patient is voluntarily providing his or her record to another entity. I'm assuming that this doesn't envision, it doesn't encompass that kind of a scenario.

Paul Egerman – Software Entrepreneur
Probably not. It's a little tricky, but if it's directly going from an individual patient interacting with a DME supplier or somebody, that's not what this scenario is. It might be, however, if the patient is interacting with some organization that maintains their PHR, and they're directing that PHR to send something to somebody else.

Jim Borland – SSA – Special Advisor for Health IT, Office of the Commissioner
Right.

Paul Egerman – Software Entrepreneur
Then it would be.

Jim Borland – SSA – Special Advisor for Health IT, Office of the Commissioner
It would come into play between the two participating organizations.

Paul Egerman – Software Entrepreneur
Between the organizations. That's correct. But the contact from the patient to something is not part of this recommendation.

Jim Borland – SSA – Special Advisor for Health IT, Office of the Commissioner
Right, so one of the things that made me think about is the idea of auditability and the idea of auditability, in other words, giving the patient the ability to know who has access to their record and not just down one level, but down multiple levels, and that gets to Paul's question.

Paul Egerman – Software Entrepreneur
That's right. Auditability and also what's sometimes called accounting for disclosures where you need to track everything. That's also an area that we are going to be identifying; we are going to be addressing in greater detail. But the basic concept will be very simple is yes … this is very simple. Yes, you need to

track all this. But when you go through that whole process, you discover it sometimes very hard to do it in a way that makes sense to the patient because when you track everything, you see there's like 50, 60, hundreds of people accessing this record for some reason. It's sometimes hard to understand exactly what to audit, but I agree. The auditability is part of the way to address the issue that Paul Tang is talking about because every time it's sent somewhere, there needs to be a track record of when and where and who it was sent to.

Deven McGraw - Center for Democracy & Technology – Director
Right, but just to be clear, we're not addressing auditor accounting of disclosures in these recommendations.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Does your recommendation to prevent the need for authenticating the receiver of data, as it goes down the various paths?

Deven McGraw - Center for Democracy & Technology – Director
Our recommendation says that if you were trying to create a mechanism for assuring organization-to-organization, we already have a requirement, if you are covered under HIPAA, or you're a business associate, that you are responsible any time you send information out the door to send it in a way that is secure. Our recommendations here set up a mechanism where that infrastructure doesn't quite exist, as opposed to Larry's example where they've worked very hard with their business partners to make sure that it does. I'm not sure what you're trying to add here, Paul.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
It's for the patient to understand where their information has gone, no matter….

Deven McGraw - Center for Democracy & Technology – Director
I think it's a separate topic that we need to take up in our set of transparency recommendations. I think it would be, only because it's very complicated a discussion, and I think I would be reluctant to attach it to this set of recommendations, which are some pretty simplistic ones on just authenticating from organization-to-organization and making sure it's the right – it's sent to the right place, which is sort of the entry gateway into a whole lot of other sort of complicated privacy and security questions. We did get some recommendations from some of our commenters to say you need to make sure, when you send it to somebody, that they're doing X, Y, and Z. And again, we acknowledged that there's this sort of complicated set of concerns around privacy and security and health information exchange, but we were reluctant to use the authentication process as the lynchpin for holding that down because we thought there were better places, such as requirements for transparency, requirements for auditing, etc. But I for one am not comfortable with layering this with a specific recommendation regarding an audit trail or accounting of disclosure without thinking of it in more detail.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
I think we aren't, I don't think Jim and I are talking about anything policy other than authentication. We're just trying to make sure that this requirement for digital certificate doesn't expire with the first transaction, the first transmission.

Paul Egerman – Software Entrepreneur
No, it does not.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
That's what we're trying….

Paul Egerman – Software Entrepreneur
No, it does not.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
You would need that in the future to audit.

Paul Egerman – Software Entrepreneur
That's correct. It does not. You have the audit protection. But you also have the requirement that we already approved that a provider is always responsible for authenticating who it's sending to. Again, we're just saying this is how you should do it. We're answering a very narrow, technical question.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Marc?

Marc Probst – Intermountain Healthcare – CIO
Quickly, to make sure I understand, and it takes a while, this recommendation is that because we know there's secure transfer of information already. There are other ways to do that. Is this recommendation an alternative? This would be the preferred alternative? These are the requirements for that alternative, or this is how all transfer of information, sharing of information needs to be done? It's a requirement for how it all will be done in the future?

Paul Egerman – Software Entrepreneur
I don't think you can say it's a requirement of how it will all be done, any more than you would say that when you develop a standard for HL-7 2.5.1 is necessarily a requirement of how you're going to do all laboratory results. But by establishing this as a standard in certification criteria, what it does is it creates an environment where you know anybody who purchases a certified EHR system is going to end up with one of these digital certificates. As a result, you have a mechanism to speak to that person from one EHR system to another. I think that's all it does.

Marc Probst – Intermountain Healthcare – CIO
Stated in what you just said, there could be other mechanisms to do it, and we know the requirement is it has to happen with security and privacy.

Paul Egerman – Software Entrepreneur
Certainly, as I said in my answer to Larry's comment, you don't have to redo what you already have done, and it doesn't create a situation where you're forced to do everything this way. But I suspect that most people know that the digital certificates, this is not controversial stuff. There's not 20 different ways you can do this. There's sort of like an obvious way to do it, and there's just some detail though to make sure we can figure out what is the information in the certificate and how it works.

Marc Probst – Intermountain Healthcare – CIO
Yes. I think the key in the statement is digital certificate isn't used in any transfer of information and that it doesn't have to be to still accomplish the requirements of HIPAA.

Paul Egerman – Software Entrepreneur
That's correct.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Any other questions or comments? We're ready to vote then. You have six recommendations, right?

Deven McGraw - Center for Democracy & Technology – Director
With the typos corrected and clarification on the meaningful use.

Paul Egerman – Software Entrepreneur
Typos corrected and the clarification to change meaningful use to electronic healthcare transactions.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Okay. Anyone want to make a motion?

M
So moved.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Second?

M
Second.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Any further discussion? All in favor?

M
Aye.

M
Aye.

M
Aye.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
And opposed? And abstained? Good. Thank you very much, Deven and Paul.

Paul Egerman – Software Entrepreneur
Thank you.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
I think we're now ready to move on to public comments.

Judy Sparrow – Office of the National Coordinator – Executive Director
Yes. If anybody in the room wishes to make a public comment, if you could please come up to the microphone once Deven and Paul vacate. And if you're on the phone already, you can just push star, one, and let me wait just a moment here. If you're on the computer, you need to dial 1-877-705-6006. Please state your name, your organization, and there's a three-minute time limit. Carol Bickford?

Carol Bickford – American Nurses Association – Senior Policy Fellow
Carol Bickford, American Nurses Association. I want to bring to the attention of the workgroup that's addressing the individual provider to be sure to encompass clinicians besides physicians in the conversation. We're talking about 3.1 million registered nurses that have to be considered, along with our other colleagues that are not physicians.

Judy Sparrow – Office of the National Coordinator – Executive Director
Is there anybody on the phone? All right. We'll take the question in the room.

Samantha Burch – Federation of American Hospitals – Dir. Health Care Policy & Research
Samantha Burch, Federation of American Hospitals. I just wanted to make a couple of comments on behalf of the federation and really appreciate this opportunity around the work of the privacy and security tiger team. The federation has concerns with some of the discussions that are taking place in the tiger team about potential areas for recommendations that may be outside of the scope of the authority that was given to HHS by Congress and the HITECH law. An example of this would be discussions around informed consent for treatment, payment, and operations, and other exchanges outside of HIPAA that seem to be on the table for potential recommendations. Consent was not required under HITECH, and it's not required for treatment, payment, and operations under HIPAA, so this is a concern.

As you know, HIPAA was strengthened under HITECH, and rulemaking is underway by the Office of Civil Rights to implement those modifications. We do not believe that meaningful use is the appropriate

vehicle for rewriting HIPAA, which is already a stringent federal law that providers go to great lengths to comply with. Finally, we believe the tiger team could really benefit from greater hospital, clinic, and academic research representation to bring maybe greater balance to some of the discussions. Again, thank you for the opportunity to comment.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, Ms. Burch. We don't have any callers on the phone, so Dr. Tang.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Thank you very much. It looks like we've pushed some decisions into December, so I think December will have really a heavy agenda, so you can count on it starting at 9:00.

Judy Sparrow – Office of the National Coordinator – Executive Director
Yes.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Just to remind everybody, the December meeting, December 13th is face-to-face. It's not virtual, so it will start at 9:00 here. Any other last minute comments? If not, thank you very much for your attendance, participation, and thanks to the public.

Public Comment Received During the Meeting

1. How would all this apply to HIM professional role?

2. Once it gets to the organization (like the provider) it goes into the EHR and then we have logs on who looks at what, when?

3. ELPD Says that Health care Provider Organizations are hospitals, clinics, nursing homes, labs...what about group practices. What about my solo practice that has an EMR etc. If the entity defines the entity level on its own... what does that mean for Quality (all of partners versus Revere Health Center), for Public health, For Patients, patient consent (say patient says yes to Braford pediatrics, but not to all of Yale new haven health system)

4. To the HIT Policy Committee:

Greetings,

Theft and impersonation of provider entities is a major risk, as detailed in the following report by the DOJ.

http://www.justice.gov/dag/pubdoc/hcfacreport2009.pdf

I would be happy to explain to the committee why it would be logical to create the provider entity directory under the c=US X.500 object, which is non-governmental, reference a separate functioning registration authority that guarantees both uniqueness and persistence in perpetuity, while allowing changes to be made at a local operational level. In addition it would be compatible with the Federal Bridge PKI naming context, have native X.509v3 support for authentication (digital certificates), and support for state level operations. It was piloted by the NSF starting in 1993 and has an extensive track record for secure operations in intelligence, major corporations, and telecommunications at recognized high levels of assurance.

I think you find this is a much more direct approach than DNS, consistent with ITU and IETF standards, that will scale for a provider entity directory for the U.S., inclusive of govermental and commercial entities that transmit, receive and route HIPAA covered data in a way that will achieve consensus. Most current software has the ability to do an LDAP query to receive results, if connected to a directory capable of doing chaining or referrals, ideally the directory of that organization. If the DNS needs to be used, a SRV record can indicate the location of that directory.

Here is an example.

CN = Google Internet Authority
O = Google Inc
C = US

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